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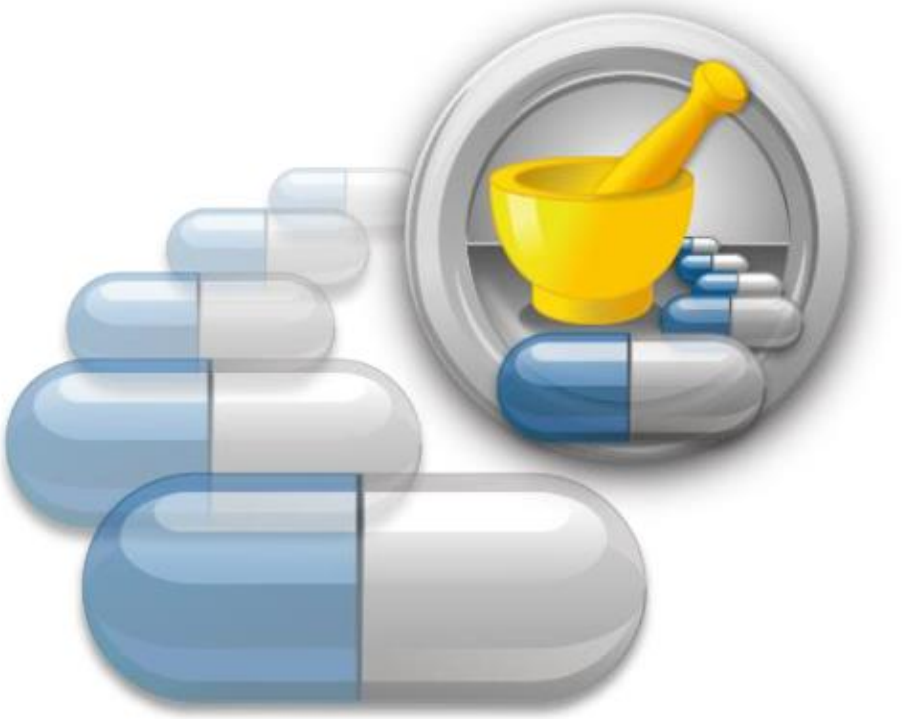

OUTPUT WEIGHING

RELEASE 11.01.00

FUNCTIONAL REQUIREMENT SPECIFICATION

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Contents

Figures

1 Introduction

This document details the requirements of the functions implemented by the Output Weighing phases of PharmaSuite. The phases are executed as an Output Weighing operation in the Production Execution Client for EBR.

Each requirement is composed of a name (e.g., Required number of sublots) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] (GID-2667883)

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface	Designates user interface texts, such as ▪ window and dialog titles ▪ menu functions ▪ panel, tab, and button names ▪ box labels ▪ object properties and their values (e.g., status).
Monospaced typeface	Designates code examples.

2 Recipe Structure for Output Weighing

This section provides an overview of weighing of produced material (Output Weighing). In addition, the yield and the prorate factor can be calculated, if a planned quantity has been defined for the output material.

In order to support different use cases, several Output Weighing operations can be modeled within one unit procedure in sequence or in parallel. This allows, e.g. to prepare containers or sublots and to weigh the produced material in a later separate step or to directly weigh the produced material without preparing any containers or sublots. For details, see "Use Cases" (GID-2668467).

PharmaSuite also supports other weighing-related scenarios. For pre-dispensing for process orders (Dispense) and Inline Weighing before charging, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] (GID-2668114)For cost center-related dispensing, see "Functional Requirement Specification Workflow Phases" [A2] (GID-2668114).

2.1 Phases

An Output Weighing operation holds the phases specific to Output Weighing. A process parameter of the **Manage produced material** phase defines the operation mode of the operation: The **Flexible** mode allows to both prepare and weigh a container or sublots; the **Prepare only** mode only allows to prepare containers or sublots.

The following phases are available for Output Weighing:

- Manage produced material (GID-2668053)
  The **Manage produced material** phase (O Manage Produced Material) allows an operator to manage produced material on container and/or sublot level.
- Show GHS data (optional, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] (GID-2668114))
  The **Show GHS data** phase allows an operator to display the GHS data defined for the current material.
- Select scale (GID-2668063)
  The **Select scale** phase (O Select Scale) allows an operator to select a weighing method and an appropriate scale. Upon phase completion, the connected scale is initialized and zeroed.
- Identify container (GID-2668073)(optional)
  The **Identify container** phase (O Identify Container) allows to identify an equipment entity (container) for the material to be produced and to bind this entity to the context in which it is being used. Appropriate equipment requirements can be defined in support of the fit-for-purpose checks during execution.
  The usage of the **Identify container** phase during **Output Weighing** is optional. It can also be used during **Dispense** and **Material Tracking**, but it must not be used during **Inline Weighing**.

- Tare (GID-2668083)
  The **Tare** phase (O Tare) allows an operator to record the actual tare of a target container.
  If an already prepared container or sublot has been identified, the phase sends the already known tare value to the connected scale and completes automatically.
- Weigh (GID-2668094)
  The **Weigh** phase (O Weigh) allows an operator to record the actual weight of a target container or sublot and to print a label for it.
  If the Output Weighing operation runs in the **Prepare only** mode, the **Weigh** phase completes automatically. In case no target container has been identified before with the **Identify container** phase, the **Weigh** phase creates a sublot in the **Prepared** status with zero quantity.
- Load logistic unit (optional, see "Functional Requirement Specification Dispense and Inline Weighing" [A3] (GID-2668114))
  The **Load logistic unit** phase allows an operator to load sublots or a logistic unit onto a target logistic unit.
  The usage of the **Load logistic unit** phase during **Output Weighing** is optional. It can also be used during **Dispense** and **Material Tracking**, but it must not be used during **Inline Weighing**.
- Release scale (GID-2668104)
  The **Release scale** phase (O Release Scale) checks whether the scale value returns back to zero after unloading.

The phases listed above support the concept of fall-through in order to handle unexpected issues that require the operator to rollback the current work with the **Return to material management** user-triggered exception. The **Show GHS data** phase supports fall-through without a specific user-triggered exception.

2.2 Weighing Methods

The following weighing methods are available:

- In **Net weighing**, first the tare weight of the target vessel is weighed. Then, the produced material is filled into the target vessel and weighed.
  Net weighing is available for Output Weighing operations that run in the **Prepare only** mode.
- In **Gross weighing**, first the filled source vessel is placed on the scale. Then, the tare of the source vessel is entered manually and the source vessel is weighed.
  Gross weighing is neither available for Output Weighing operations that run in the **Prepare only** mode nor for container or sublot preparation in the **Flexible** operation mode.
- In **Pallet weighing**, first the loaded pallet is placed on the scale. Then, the tare of the pallet and of one of the vessels it holds are entered manually, along with the number of vessels. Finally, the loaded pallet is weighed.
  (**Pallet weighing** is based on the assumption that all vessels on a pallet have the same tare.)
  Pallet weighing is neither available for Output Weighing operations that run in the **Prepare only** mode nor for container or sublot preparation in the **Flexible** operation mode.
  Pallet weighing does not apply to the **Identify container** phase.

- In **Quantity entry**, no physical scale is used at all. The quantity provided by external means has to be entered manually.
  Quantity entry is available for Output Weighing operations that run in the **Prepare only** mode. The **Tare** and **Release scale** phases are skipped in this weighing method.

2.3 Equipment Management Integration

Since PharmaSuite 8.1 (and Output Weighing phases (RS) [5.0]), equipment management is integrated into PharmaSuite and its phase building blocks. Equipment management covers containers (GID-2668460), scales (GID-2668461), and the handling of runtime properties during exceptional situations (GID-2668462).

2.3.1 Containers

The system supports the management of target containers in the context of Output Weighing.

Containers are maintained based on the flexible S88 equipment management capability (see "Functional Requirement Specification Data Management" [A4] (GID-2668114). A container must be of the **Container (RS)** equipment type and a graph of the **Container Cleaning RS)** purpose must be assigned to it.

Specific phases take care of container binding and automatic status graph transitions. In case a status transition fails, the phase requires to sign the **Status transition failed** system-triggered exception.
In addition, phases can write, read, or clear runtime properties of a container with the **Current Tare (RS)** or **Current Sublot (RS)** purposes. The **Tare** phase can read the container's runtime property of the **Reference Tare (RS)** purpose and uses the value for the optional tare value check.

For details, refer to the business logic section of the following phases:

- **Manage produced material** phase: **Container management (SR0700.2.6)** function (GID-2669870)
- **Tare** phase: **Container management (SR0720.2.10)** function (GID-2669969)and **Check container tare (SR0720.2.13)** function link
- **Weigh** phase: **Container management (SR0730.2.10)** function (GID-2670006)

2.3.2 Scales

Scales are maintained based on the flexible S88 equipment management capability (see "Functional Requirement Specification Data Management" [A4] (GID-2667986). A scale must be of the **Scale (RS)** equipment type and graphs with the **Scale Test (RS)** and **Scale Calibration (RS)** purposes must be assigned to it.

Specific phases take care of scale binding, e.g. binding upon scale selection and unbinding after the weight has been recorded.
Upon selection of a scale with the **Select scale** phase, the system checks the scale's expiry status and, if necessary, automatically updates an expired status. If the status transition fails, the phase displays the **Expired trigger execution failed** error message and the scale can no longer be selected.
In addition, during preparation of a target container, the **Weigh** phase can be used to mark the used

scale as currently loaded (runtime property of the scale with the **Current Load (RS)** purpose). This results in skipping the zeroing of the scale (with the **Select scale** and **Get weight** phases) and skipping its release check (in the **Release scale** phase) during subsequent process steps. In order to assure proper handling of loaded scales during execution, the operator has to confirm the current load (scan of container or sublot). If the current load cannot be confirmed, the **Select scale** phase does not allow to select an already loaded scale and the **Get weight** phase does not allow to skip zeroing.
If a scale is used that is configured as manual scale, no automated scale communication takes place. During execution, all scale values have to be entered manually and a phase completion signature is automatically requested according to the system configuration.

For details, refer to the business logic section of the following phases:

- **Manage produced material** phase: **Scale management (SR0700.2.7)** function (GID-2669871)
- **Weigh** phase: **Scale management (SR0730.2.11)** function (GID-2670007)

2.3.3 Handling of Runtime Properties during Exceptional Situations

The Output Weighing phases provide specific exceptions that have an impact on the involved equipment objects. In general, the current status and/or context information is reset when such an exception is recorded, e.g. a **Return to material management** user-triggered exception.
For details, please refer to the sections "Equipment Management" of the **Manage produced material** phase (GID-2668472), the **Tare** phase (GID-2668083), and the **Weigh** phase (GID-2668094).

However, the value of a runtime property is never reset automatically by the system when an exception is recorded, because most likely this also requires further process steps on the shop floor. Runtime properties, in case they have to be reset manually as a consequence of such an exceptional situation, always need to be updated by a data administrator in Data Manager (or alternatively along with the execution of a respective clean-up-workflow on the shop floor, if enabled by project-specific phases).

The table below lists the exceptions and related runtime properties that may require a manual reset/update after an exception has been recorded:

Phase	User-triggered exception
Manage Produced Material Phase (SR0700+) (GID-2668053)	Annul prepared sublot (SR0700.3.1.3) link ▪ Container's property of the **Current Tare (RS)** purpose ▪ Scale's property of the **Current Load (RS)** purpose Replace weighed sublot (SR0700.3.1.4) (GID-2669889) ▪ Container's property of the **Current Sublot (RS)** purpose ▪ Container's property of the **Current Tare (RS)** purpose

2.4 Planned Quantity Modes and Application of a Prorate Factor

For Output Weighing, the system supports specific features related to several planned quantity modes and the application of a prorate factor in case a planned quantity has been defined.

2.4.1 Planned Quantity Modes

For a material output parameter of a phase, the following planned quantity modes can be defined:

- **As defined** requires a planned quantity and tolerances to be defined in the recipe.
  During execution, the planned quantity is based on the recipe definition and a prorate factor can be applied.
- **None** means that no planned quantity is relevant during execution. Any planned quantity defined in the recipe will be ignored.
  During execution, the planned quantity is stated **N/A** and no planned quantity-related checks apply.
  Subsequently, no yield and prorate factor can be calculated for the specific output material, because both calculations are based on a planned quantity.

2.4.2 Application of a Prorate Factor

The application of a prorate factor is used to automatically reduce the planned quantity of input and output materials of a current unit procedure, based on the yield calculation of produced output materials from one or more preceding unit procedures.

Yield and prorate factor for a produced material can only be calculated if a planned quantity was defined in the recipe for the related output material. The prorate factor is calculated as follows:

Prorate factor = Actual produced output quantity / Original planned output quantity
(For details, see **Output Weighing done (SR0700.2.3)** business logic (GID-2669867).)

The **Manage produced material** phase for Output Weighing provides the **Prorate factor (SR0700.8.6)** process parameter (GID-2671997)to control the application of the prorate factor to output materials during execution. The process parameter can be configured via information flow, which means that the process parameter can be linked directly to a **prorate factor** output variable that provides the calculated prorate factor from a preceding unit procedure.

The following rules apply when a calculated prorate factor is applied during Output Weighing:

- The prorate factor is only applied to materials with the **As defined** a planned quantity mode.
  It is not applied if the planned quantity mode of a material is **None**.
- Especially in case multiple Output Weighing operations are modeled in parallel for one output material (e.g. Prepare and Weigh, see use case "Multiple Output Material Parameters per Unit Procedure" (GID-2669852)), the **Prorate factor** process parameter must be configured identically for each of the Output Weighing operations. The factor is only applied automatically once (see bullet below). However, due to the parallel structure, it is not determined which operation is started first during execution. Therefore the prorate factor has to be configured for both Output Weighing operations.

- The prorate factor is only applied automatically once per order step output material. This occurs during the first time a **Manage produced material** phase for this output material is activated. It is not applied automatically again in another Output Weighing operation for the same output material or in later instances of a phase, e.g. due to looping or rework scenarios (new unit procedure instance).
- The prorate factor can be overridden and a new factor can be applied to an output material with the **Override prorate factor (SR0700.3.1.1)** user-triggered exception (GID-2669883). The exception is available as long as the **Done** option of the **Manage produced material** phase is not selected. As a result, the planned quantity of the output material is updated, which is used as the baseline for the yield calculation for the output material.
- **Note**: In case two or more Output Weighing operations are modeled in parallel for one output material (e.g. Prepare and Weigh, see use case "Only One Output Material Parameter per Unit Procedure" (GID-2669851)) and the prorate factor, in violation of this guideline, is not modeled for the first operation that becomes active, no automatic application of the prorate factor happens at this time.
  However, the prorate factor could already be set manually with the **Override prorate factor (SR0700.3.1.1)** user-triggered exception (GID-2669883). In this case, the prorate factor is already set once and therefore is no longer applied automatically once other Output Weighing operations for the same output material become active.

2.5 Output Weighing Operation

The typical structure of an Output Weighing operation includes all Output Weighing phases (GID-2668048)in a graph with a loop and a completion-related branch controlled by transitions (GID-2668465).
The usage of the **Show GHS data** phase, **Identify container** phase, and the **Load logistic unit** phase is optional.

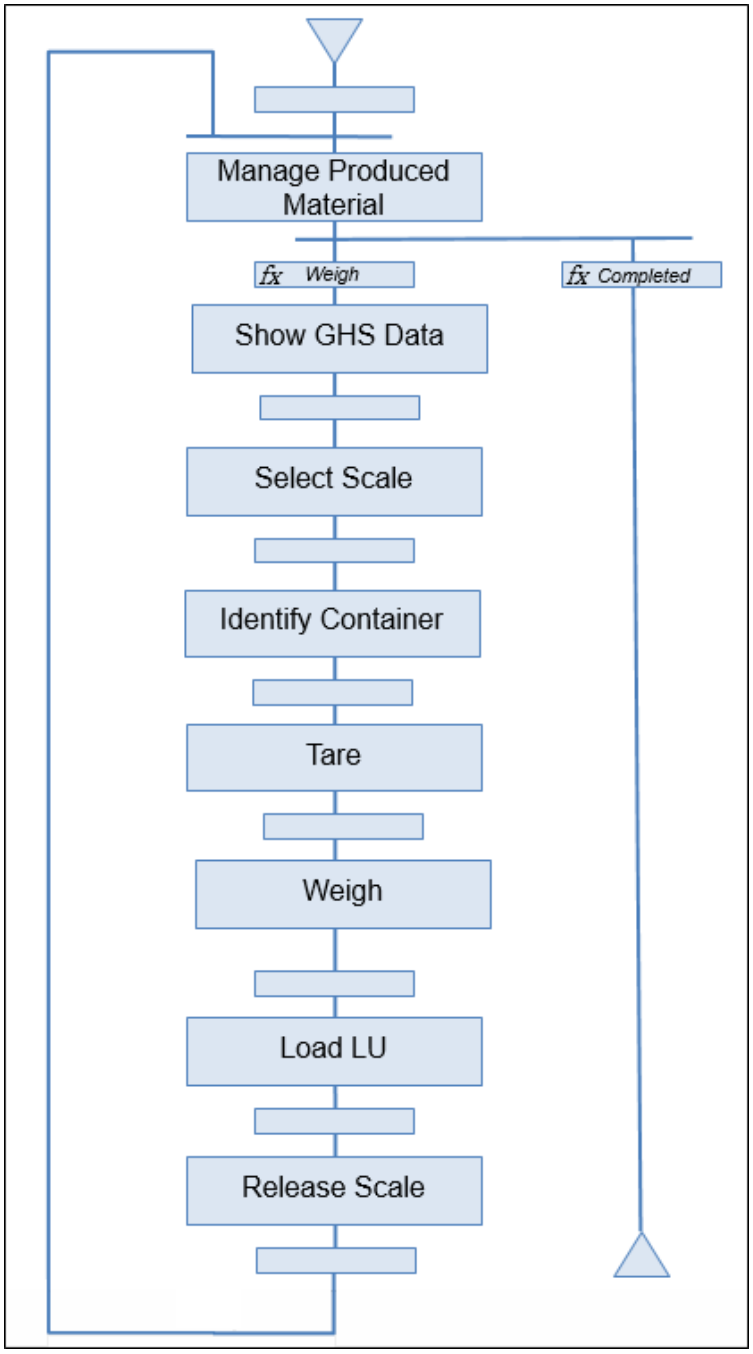

Figure 1: Typical Output Weighing operation with a loop and a completion-related branch

The behavior of the phases can be affected by exceptions and the applied weighing method (GID-2668049).

2.5.1 Transitions

Transitions make use of the output variables of a phase to control the process.
The usage of the **Show GHS data** phase, **Identify container** phase, and the **Load logistic unit** phase is optional.

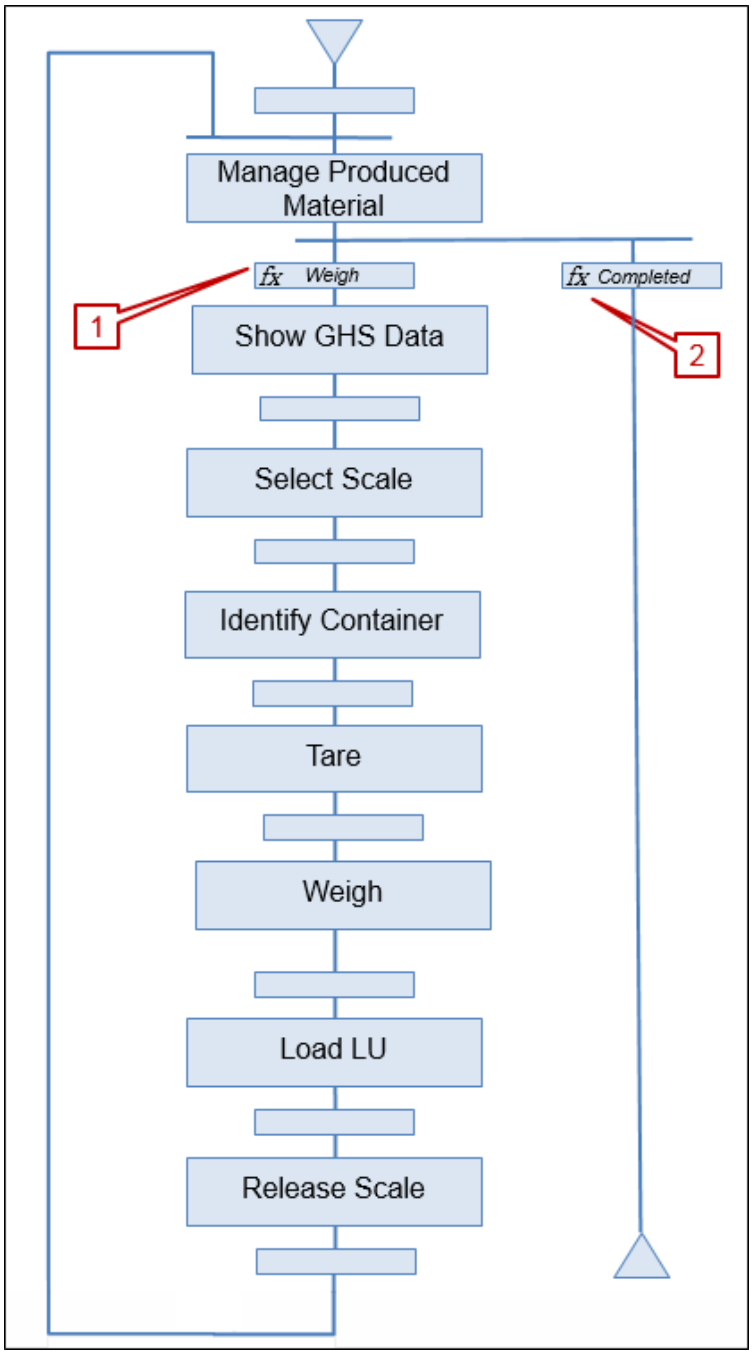

Figure 2: Transitions in a typical Output Weighing operation

The transitions make use of specific data that is provided via information flow:

- **Result** output variable of the **Manage produced material** phase: WEIGH, COMPLETED

1. Weigh (Manager Produced Material » Select Scale)
   {Manage Produced Material}.{Result} == "WEIGH"
2. Completed (Manage Produced Material » End step)
   {Manage Produced Material}.{Result} == "COMPLETED"

2.5.2 Exceptions

Each phase provides a set of exceptions to record irregular circumstances.

Phase	Exception
Manage Produced Material Phase (SR0700+) (GID-2668053)	User-triggered exceptions: Override prorate factor (SR0700.3.1.1) (GID-2669883) Identify manually (SR0700.3.1.2) (GID-2669885) Annul prepared sublot (SR0700.3.1.3) (GID-2669887) Replace weighed sublot (SR0700.3.1.4) (GID-2669889) System-triggered exceptions: Violated number of sublots (SR0700.3.2.1) (GID-2669877) Overweight check (SR0700.3.2.2) (GID-2669878) Underweight check (SR0700.3.2.3) (GID-2669879) Status transition failed (SR0700.3.2.5) (GID-2669881)
Show GHS Data Phase (SR0380+) (GID-2667798)	See "Functional Requirement Specification Dispense and Inline Weighing" [A3] (GID-2668114).
Select Scale Phase (SR0710+) (GID-2668063)	User-triggered exceptions: Return to material management (SR0710.3.1.1) (GID-2669911) Select offline scale (SR0710.3.1.2) link Confirm scale load manually (SR0710.3.1.3) (GID-2669915)
Identify Container Phase (SR0750+) (GID-2668073)	User-triggered exceptions: Enter identifier manually (SR0750.3.1.1) (GID-2669941) Unbind (SR0750.3.1.2) (GID-2669943) Skip container identification (SR0750.3.1.3) (GID-2669945) Return to material management ((GID-2669947)) link System-triggered exceptions: Property value check (SR0750.3.2.1) (GID-2669932) Container status check (SR0750.3.2.2) (GID-2669934) Unforeseen resume (SR0750.3.2.4) (GID-2669937) Status transition failed (SR0750.3.2.4) (GID-2669937)
Tare Phase (SR0720+) (GID-2668083)	User-triggered exceptions: Return to material management (SR0720.3.1.1) (GID-2669980) Redo zero (SR0720.3.1.2) (GID-2669982) Use offline tare (SR0720.3.1.3) (GID-2669983) System-triggered exceptions: Failed tare check (SR0720.3.2.2) (GID-2669976) Unforeseen resume (SR0720.3.2.1) (GID-2669978)

Phase	Exception
Weigh Phase (SR0730+) (GID-2668094)	User-triggered exceptions: Return to material management (SR0730.3.1.1) (GID-2670021) Enter weight manually (SR0730.3.1.2) (GID-2670023) Override use-by date (SR0730.3.1.4) (GID-2670025) Warehouse error (SR0730.3.1.5) (GID-2670027) System-triggered exceptions: Status transition failed (SR0730.3.2.1) (GID-2670017) Unforeseen resume (SR0730.3.2.2) (GID-2670015) Out of tolerance (SR0730.3.2.3) (GID-2670019) Post-completion exceptions: Reprint label (SR0730.3.3.1) (GID-2670029)
Load Logistic Unit Phase (SR0390+) (GID-2667839)	See "Functional Requirement Specification Dispense and Inline Weighing" [A3] (GID-2668114).
Release Scale Phase (SR0740+) (GID-2668104)	User-triggered exceptions: Enter scale value manually (SR0740.3.1.1) (GID-2670053) System-triggered exceptions: Release was not successful (SR0740.3.2.1) (GID-2670049) Unforeseen resume (SR0740.3.2.2) (GID-2670051)

2.5.3 Use Cases

In order to support different use cases, several Output Weighing operations can be modeled within one unit procedure in sequence or in parallel. However, **not all use cases are supported at the same time**, which finally depends on the number of output materials to be produced within one unit procedure.

In general, the preparation of target sublots for the material to be produced requires that either at least one source sublot of the input material has already been identified with the **Identify material** phase or that a prepared target sublot for the target batch is created automatically with the **Weigh** phase without identification. However, if a target container that is managed within PharmaSuite has been identified for preparation, the preparation is no longer based on a target sublot, but on the identified container, and no restrictions apply anymore regarding the identification of input material. In this case, the system supports the preparation of a container prior to any identification of a source sublot.

Aside from the definition of the overall planned quantity for an output material, PharmaSuite also supports Output Weighing against a pre-defined target weight for each sublot that is created during the Output Weighing process.

2.5.3.1 ONLY ONE OUTPUT MATERIAL PARAMETER PER UNIT PROCEDURE

In this case, only one MFC-related output material parameter is defined for a unit procedure.

Use case characteristics:

- One order step output during runtime
- PharmaSuite supports two different scenarios: **Direct weighing** (**only one** Output Weighing operation) and **Preparation and weighing** (**two** Output Weighing operations).
  In both scenarios, the operations have to be configured to run in a specific operation mode (**Prepare only** or **Flexible**). The operation mode is defined with the **Operation mode (SR0700.8.12)** process parameter (GID-2671996)of the **Manage produced material** phase.

Scenario: **Direct weighing** of sublots in one process step:

- One Output Weighing operation is modeled within one unit procedure.
- The operation runs in the **Flexible** operation mode.
- The phases are optimized to tare (except for **Quantity entry**) and directly weigh a sublot in the **Net**, **Gross**, **Quantity entry**, or **Pallet** weighing methods. Target container management is supported in the **Net**, **Gross**, and **Quantity entry** weighing methods.
- In addition, the system allows to first tare and prepare new containers or sublots and, in a later instance of the phase, identify and weigh an already prepared container or sublots, all within the same Output Weighing operation.
- The operation can only be completed without exceptions if the checks against the planned quantity and the final number of recorded containers/sublots have passed (see **Confirm by button (SR0700.2.5)** function (GID-2669869)). In addition, no remaining containers or sublots in the **Prepared** status are allowed.
- In case a planned quantity has been defined, upon completion of the phase, yield and prorate factor are calculated and made available for subsequent processing steps via information flow.

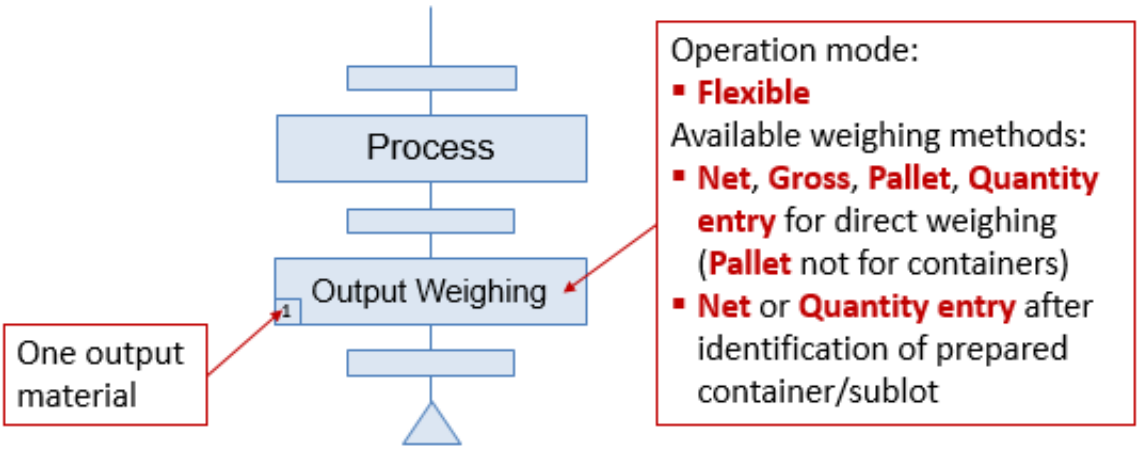

Figure 3: Scenario: Direct weighing of a container/sublots in one process step

Scenario: **Preparation and weighing** of sublots in two separate process steps:

Two Output Weighing operations are modeled in sequence or in parallel.

The MFC-relevant output material parameter must be defined only for one of the Output Weighing operations, which typically is the one used for weighing. All other Output Weighing operations run against the one unique order step output automatically.

The first operation runs in the **Prepare only** operation mode. In this mode, the system only allows containers or sublots to be tared and prepared, but not to be weighed. The **Pallet** and **Gross** weighing methods are not available for the preparation of containers or sublots.
The operation can be completed without exceptions as soon as the required number of containers or sublots has been prepared. Yield and prorate factor are not calculated in the **Prepare only** mode.

The second operation runs in the **Flexible** operation mode. In this mode, a previously prepared container or sublots can be identified and weighed. In addition, the system still allows to tare and prepare a new container or sublots or to tare and directly weigh a container or sublot.
The operation can only be completed without exceptions if all checks against the planned quantity and the final number of recorded containers/sublots have been passed (see **Confirm by button (SR0700.2.5)** function (GID-2669869)). In addition, no remaining container or sublots in the **Prepared** status are allowed.
In case a planned quantity has been defined, upon completion of the phase, yield and prorate factor are calculated and made available for subsequent processing steps via information flow.

In case two or more Output Weighing operations are modeled in parallel and they run in the same operation mode (**Prepare only** or **Flexible**), the same rules for completing the operation apply as for the first Output Weighing operation that runs in the same operation mode.

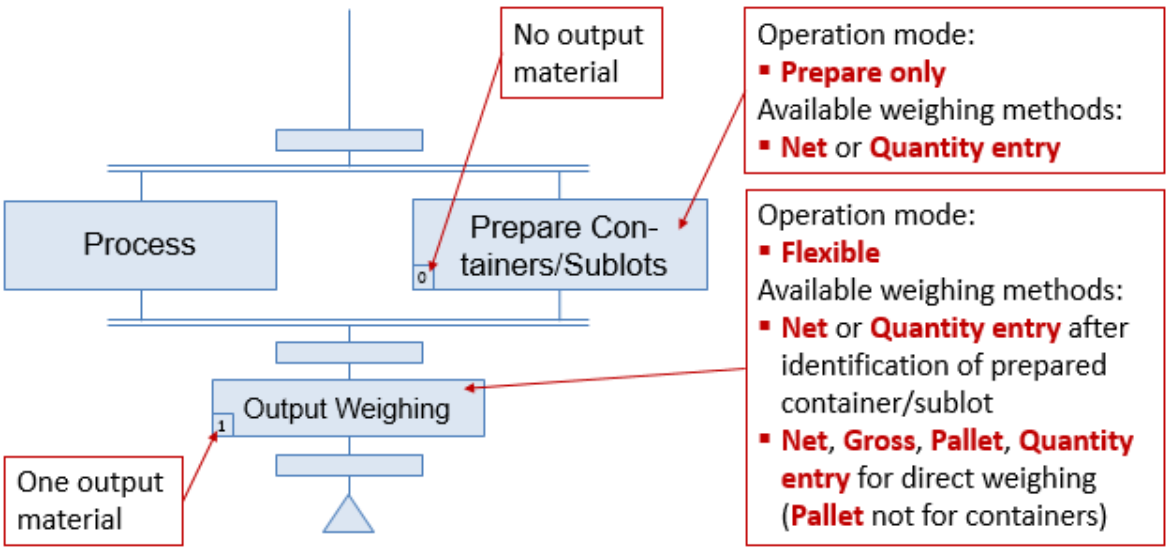

Figure 4: Scenario: Direct weighing of a container/sublots in one process step

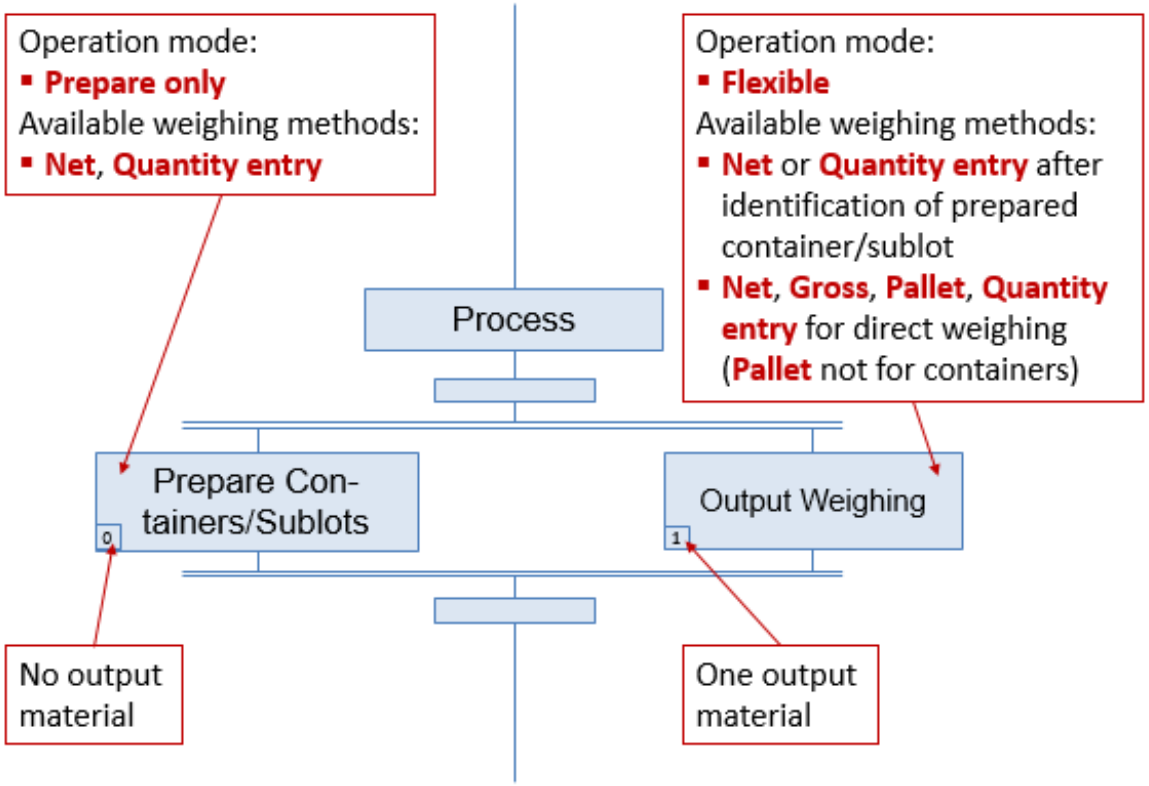

Figure 5: Scenario: Direct weighing of a container/sublots in one process step

2.5.3.2 MULTIPLE OUTPUT MATERIAL PARAMETERS PER UNIT PROCEDURE

In this case, two or more MFC-related output material parameters are defined for a unit procedure. Different material parameters can refer to the same material.

Use case characteristics:

Multiple order step outputs during runtime

PharmaSuite supports only one scenario: **Direct weighing** (**only one** Output Weighing operation per MFC-related output material).
Important: This means that Output Weighing must not be split into two or more different Output Weighing operations per output material with the **Prepare only** and **Flexible** operation mode.
The operation mode is defined with the **Operation mode (SR0700.8.12)** process parameter (GID-2671996)of the **Manage produced material** phase.

Scenario: **Direct weighing** of sublots in one process step (main scenario of this use case):

One Output Weighing operation is modeled within the unit procedure per output material parameter.

The operation runs in the **Flexible** operation mode.

The phases are optimized to tare (except for **Quantity entry**) and directly weigh a sublot in the **Net**, **Gross**, **Quantity entry**, or **Pallet** weighing methods. Target container management is supported in the **Net**, **Gross**, and **Quantity entry** weighing methods.

In addition, the system allows to first tare and prepare new containers or sublots and, in a later instance of the phase, identify and weigh an already prepared container or sublots, all within the same Output Weighing operation.

The operation can only be completed without exceptions if the checks against the planned quantity and the final number of recorded containers/sublots have passed (see **Confirm by button (SR0700.2.5)** function (GID-2669869)). In addition, no remaining containers or sublots in the **Prepared** status are allowed.

In case a planned quantity has been defined, upon completion of the phase, yield and prorate factor are calculated and made available for subsequent processing steps via information flow.

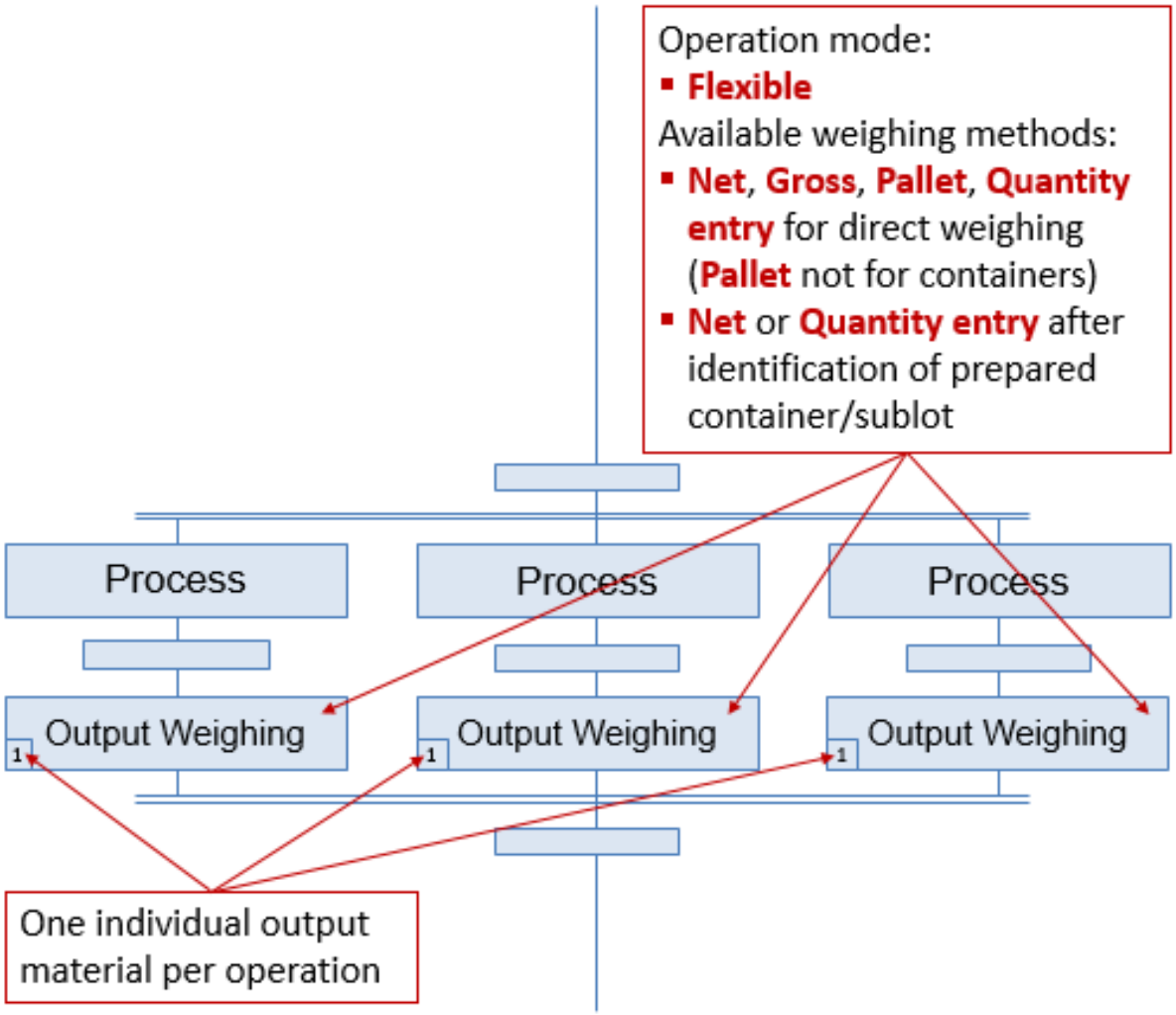

Figure 6: Scenario: Direct weighing of containers/sublots in one process step (multiple order step outputs)

3 Manage Produced Material Phase (SR0700+)

The **Manage produced material** phase (O Manage Produced Material) allows an operator to manage produced material on container and/or sublot level.
Typically, it is the first step in an Output Weighing operation. It lists all containers or sublots that have already been prepared or weighed and is executed multiple times in order to support one of the following use cases:

- Weighing a container or sublot directly
  The operator completes the phase without any further action, followed by the subsequent weighing-related steps.
- Preparing a container or sublot
  Upon completion of the phase, the operator takes the subsequent weighing-related steps: either to tare a sublot and to print a label for the empty sublot or to identify and tare a target container.
- Weighing a prepared container or sublot
  This use case requires at least one prepared container or sublot with a known tare value in the list of containers or sublots. The container or sublot can be identified (scanned) by the operator. Upon execution of the subsequent weighing-related steps, the tare value of the identified container or sublot is taken over automatically and its net weight can be recorded.
- Completing the current Output Weighing operation
  The operator explicitly declares that Output Weighing is **Done**, which means that all of the required containers or sublots have been prepared (**Prepare only** mode) or all produced materials have been weighed (**Flexible** mode).
  In this case, depending on the operation mode, certain checks apply (e.g. number of containers/sublots, planned quantity, no non-weighed containers/sublots left), calculations are triggered (yield, prorate factor), and, if configured, a phase completion signature is requested. Upon phase completion, the system leaves the Output Weighing loop.

Anomalies that occur during processing are covered by the phase exception handling (GID-2668057)(e.g. annulling a prepared sublot, manual identification, violation of checks).

After completion the phase displays specific information about the material and batch to be produced in the Execution Window. In case a container or sublot has been identified, the phase also displays the container or sublot identifier.

Details of the operator actions are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669864). In case the Output Weighing loop is completed, the sub-report and batch report contain an entire list of all the containers/sublots that hold the produced material, including their quantity information.

The Navigator displays the batch and material identifiers. In case a container or sublot has been identified, the container or sublot identifier is displayed instead.

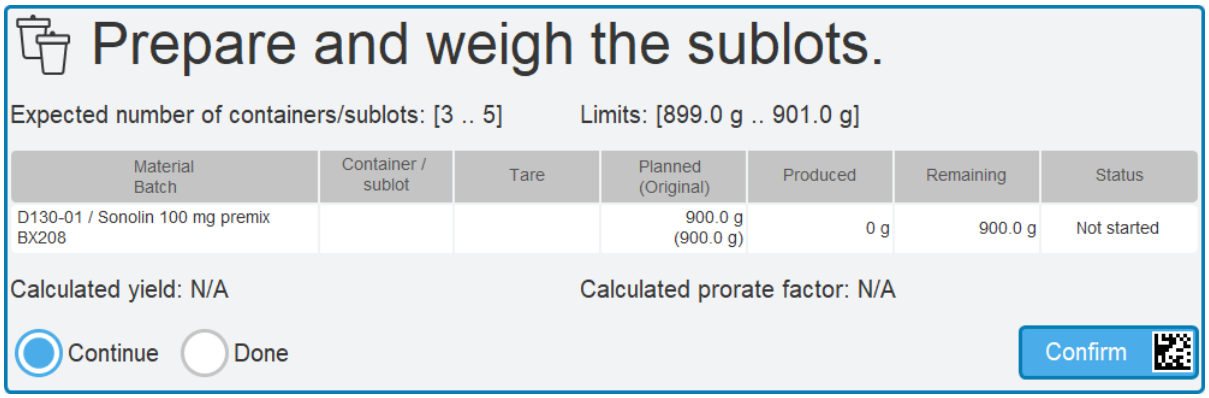

Figure 7: Manage produced material for sublots during execution (Continue)

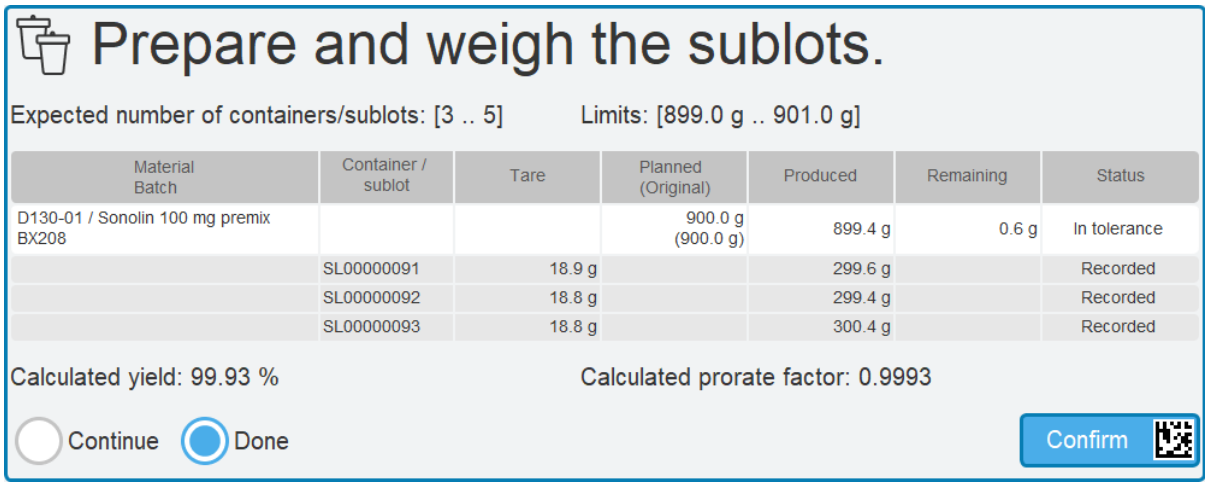

Figure 8: Manage produced material for sublots during execution (Continue)

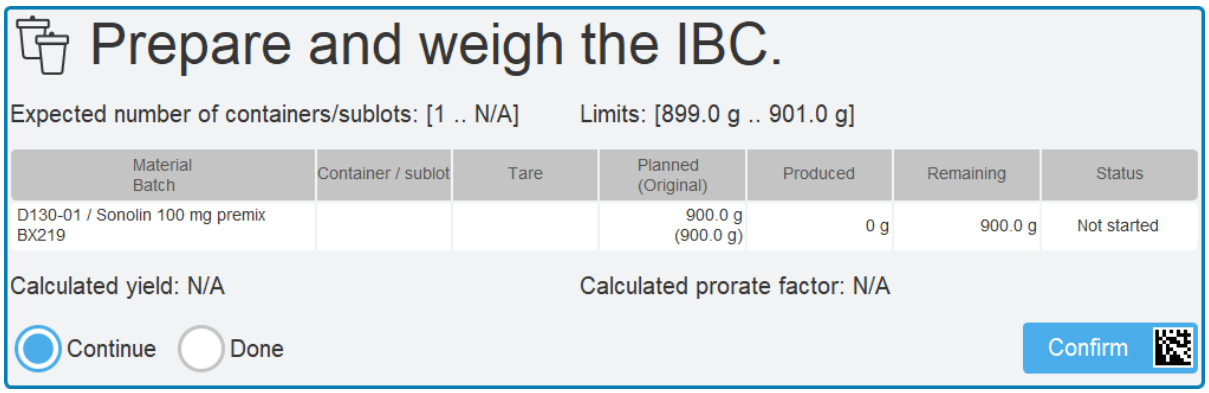

Figure 9: Manage produced material for sublots during execution (Continue)

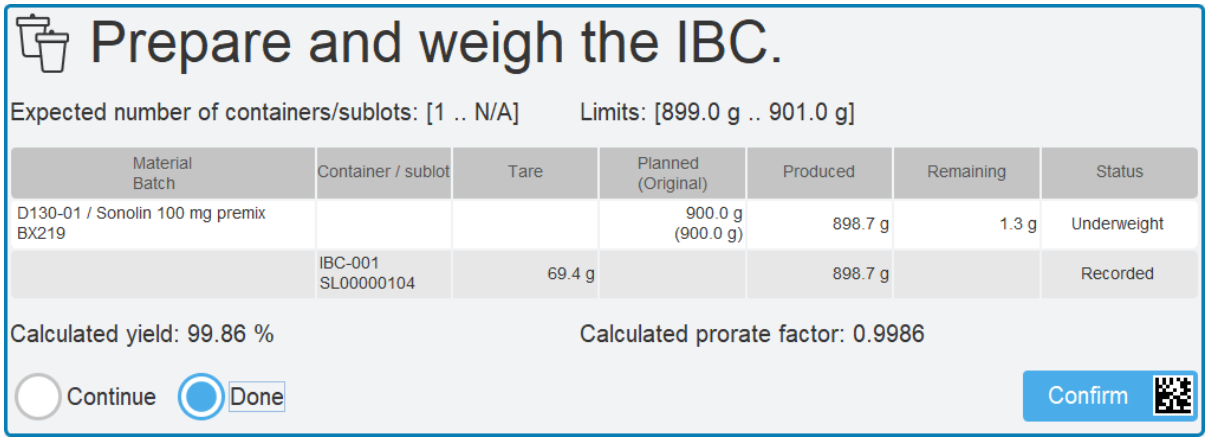

Figure 10: Manage produced material for sublots during execution (Continue)

3.1 Layout

The phase provides individual layouts for its representation during execution (GID-2668468), in the Navigator (GID-2668469), and in the sub-report (GID-2668470).

3.1.1 Representation during Execution (SR0700.1+)

The representation during execution depends on the phase mode.

3.1.1.1 GID-2669853 Preview mode (SR0700.1.1)

1. Phase-specific icon.
2. <Instruction text>
   (taken from **Instruction (SR0700.8.1)** process parameter (GID-2671995))
3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.2 GID-2669854 Active mode (Continue) (SR0700.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0700.8.1)** process parameter (GID-2671995))
4. Expected number of containers/sublots: [<value> .. <value>]
   (taken from **Number of sublots (SR0700.8.2)** process parameter (GID-2671998))

5. Limits: [<lower limit> .. <upper limit>]
   (taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
6. Produced material and a list of its containers/sublots (Table of sublots (SR0700.1.4) (GID-2669856))
   (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
7. Calculated yield: (empty, not defined yet)
8. Calculated prorate factor: (empty, not defined yet)
9. **Continue** option button and **Done** option button
   (**Continue** selected).
10. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.3 GID-2669855 ACTIVE MODE (DONE) (SR0700.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0700.8.1)** process parameter (GID-2671995))
4. Expected number of containers/sublots: [<value> .. <value>]
   (taken from **Number of sublots (SR0700.8.2)** process parameter (GID-2671998))
5. Limits: [<lower limit> .. <upper limit>]
   (taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
6. Produced material and a list of its containers/sublots (Table of sublots (SR0700.1.4) (GID-2669856))
   (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
7. Calculated yield: <value>
8. Calculated prorate factor: <value>
9. **Continue** option button and **Done** option button
   (**Done** selected).
10. **Confirm** button.

11. Phase completion signature panel
    (only if a phase completion signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.4 GID-2669856 TABLE OF SUBLOTS (SR0700.1.4)

Data available per output material:

Content	UI text	Comment
Material identifier / short description Batch identifier	Material Batch	---
Container/sublot identifier(s)	Container / sublot	Sub-rows.
Tare (containers/sublots)	Tare	---
Planned and original quantities (material)	Planned (Original)	Planned: Original quantity that might by updated by application of predecessor's prorate factor. Original: As originally defined in the recipe and calculated by order explosion.
Produced quantity (material)	Produced	Total of all produced sublots for the material item.
Produced quantity (containers/sublots)	Produced	Container/sublot-specific produced quantities.
Remaining quantity (material)	Remaining	Difference between planned quantity and recorded quantity.
Status (material)	Status	**Not started**: No containers/sublots have been prepared so far. **In process**: At least one container/sublot has been weighed. **Underweight**: Output Weighing has been completed below tolerance.

Content	UI text	Comment
		In tolerance: Output Weighing has been completed within tolerance. **Overweight**: Output weighing has been completed above tolerance. **Done**: Output Weighing has been completed with no planned quantity specified.
Status (container/sublots)	Status	**Prepared**: Container has been prepared/Sublot has been created and tare recorded, but not yet weighed. **Recorded**: Weight of container/sublot has been recorded. **Annulled**: Prepared container/sublot has been annulled with **Annul prepared sublot (SR0700.3.1.3)** user-triggered exception (GID-2669887). An annulled sublot remains in the table with its new status, an annulled container is removed from the table. **Replaced**: Weighed container/sublot has been replaced with **Replace weighed sublot (SR0700.3.1.4)** user-triggered exception (GID-2669889).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.5 GID-2669857 Completed mode (Output Weighing in process) (SR0700.1.5)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. Details of material to be produced.

- First line

<Material identifier>	<Material short description>	<Planned quantity>

- Second line (only if the target batch is already available, after the first weighing has been performed)

<Batch identifier>		<Container/sublot identifier of prepared container/sublot (only if identified)>

4. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.6 GID-2669858 COMPLETED MODE (DONE) (SR0700.1.6)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0700.8.1)** process parameter (GID-2671995))
4. Expected number of containers/sublots: [<value> .. <value>]
   (taken from **Number of sublots (SR0700.8.2)** process parameter (GID-2671998))
5. Limits: [<lower limit> .. <upper limit>]
   (taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
6. Produced material and a list of its containers/sublots (Table of sublots (SR0700.1.4) (GID-2669856))
   (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
7. Calculated yield: <value> or N/A (if no planned quantity defined)
8. Calculated prorate factor: <value> or N/A (if no planned quantity defined)
9. **Continue** option button and **Done** option button
   (**Done** selected, both disabled).
10. **Confirm** button (completed).
11. Phase completion signature panel
    (only if a phase completion signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2 Representation in Navigator (SR0700.4+)

The Navigator provides the following details:

3.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:
    Manage produced material

3.1.2.2 GID-2669860 INFORMATION COLUMN (SR0700.4.1)

- N/A / <material identifier>
  or
  <Batch identifier> (if already known) / <material identifier>
  or
  <Container/sublot identifier>, if an already prepared container/sublot has been identified.
- Example:
  BX123 / D001-03

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2.3 ACTION COLUMN

- There are no actions available.

3.1.3 Representation in Sub-report (SR0700.5+)

The sub-report contains the following information:

3.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

3.1.3.2 GID-2669863 Sub-report elements (Continue) (SR0700.5.1)

Output Weighing was still in process (**Done** option button not selected):

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Position: <number>
- Material: <identifier> / <short description>
- Batch: <identifier> (if already known)
- No container or sublot identified.
  or
  <Container/sublot identifier> container/sublot identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.3.3 GID-2669864 Sub-report elements (Done) (SR0700.5.2)

Output Weighing was completed (**Done** option button selected):

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Position: <number>
- Material: <identifier> / <short description>
  (material information taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
- Batch: <identifier>
- Planned and original quantities
- Produced and remaining quantities
- Status [of the material position]
- Expected number of containers/sublots: [<value> .. <value>]
  (taken from **Number of sublots (SR0700.8.2)** process parameter (GID-2671998))
- Limits: [<lower limit> .. <upper limit>]
  (taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
- Table of containers/sublots with the following columns from the (Table of sublots (SR0700.1.4) (GID-2669856))
  - Container/sublot [identifier]
  - Tare

- Produced [quantity of the sublot]
- Status [of the sublot position]

- Calculated yield: <value>
- Calculated prorate factor: <value>
- <Phase completion signature>
  (only if a phase completion signature is assigned to the phase)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2 Business Logic (SR0700.2+)

The phase implements the following business logic.

3.2.1 Main Path

Business logic related to the main path:

3.2.1.1 GID-2669865 Display material grid (SR0700.2.1)

- Function: Display of material grid (Table of sublots (SR0700.1.4) (GID-2669856))
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase retrieves material information from the output material of the related unit procedure.
	20	In case a prorate factor is defined (see **Prorate factor (SR0700.8.6)** process parameter (GID-2671997)) and no prorate factor has been applied for the specific output material yet (in case of multiple Output Weighing operations for the same output material), the prorate factor is applied and the planned quantity is updated accordingly (= original quantity * prorate factor). In case the prorate factor is an invalid value (not a scalar > 0), phase displays the **Invalid prorate factor (SR0200.3.4.1)** information message (GID-2668185)and the new planned quantities are updated to zero.

Step	#	Description
		The prorate factor is automatically applied only once, when the first instance of the phase becomes active. It will never be applied automatically once again, not even not as part of a new instance of the unit procedure itself. (However, the prorate factor can be set manually with the **Override prorate factor (SR0700.3.1.1)** user-triggered exception (GID-2669883).)
	30	Phase updates the related container/sublot information, including tare, status of the container/sublot-related position, and produced quantity, if applicable.
	40	In case a new produced quantity was recorded for a container/sublot, phase updates the produced and the remaining quantity of the output material position.
	50	Phase listens to barcode scanning of an already prepared container/sublot.
	60	In case the **Done** option button is selected, phase updates the status of the output material position.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.1.2 GID-2669866 SUBLOT BARCODE SCAN (SR0700.2.2)

- Function: Scan of container/sublot barcode
- Type: Main path
- Precondition: Prepared container/sublot is available. Phase's **Operation mode** is not set to **Prepare only**.
- Trigger: Operator scans barcode
- Postcondition: Phase is completed

Step	#	Description
Operator scans barcode	5	Phase reads scanned data. If phase operates in **Prepare only** mode (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)), no container/sublot can be identified and phase displays the **Prepare only (SR0700.3.6.7)** error message (GID-2668482).

Step	#	Description
	10	▪ If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading. ▪ If barcode reading was technically not successful, phase remains in listening mode. ▪ If barcode reading was not successful, phase displays the **Invalid barcode (SR0700.3.6.1)** error message (GID-2669890).
	30	Phase performs business-related checks listed below.
	40	If one of the following checks is violated, phase displays an error message: ▪ **Done** mode-related check Phase must not be in **Done** mode, **No sublot identification (SR0700.3.6.8)** error message (GID-2668488). ▪ Sublot-related check Sublot must exist, **Sublot does not exist (SR0700.3.6.3)** error message (GID-2668484). ▪ Container/sublot-related check Container/sublot must be prepared, **Sublot is not prepared or cannot be replaced (SR0700.3.6.2)** error message (GID-2668483)or **Container not prepared or recorded for this order step output (SR0700.3.6.10)** error message (GID-2668489). ▪ Container/sublot-related check Container/sublots must be prepared for the current order step (**CheckSublotProducedByOtherOSO_0** check), **Sublot for different order step (SR0700.3.6.5)** error message (GID-2668486)or **Container not prepared or recorded for this order step output (SR0700.3.6.10)** error message (GID-2668489). ▪ Sublot-related check Sublot must not be logically deleted (**CheckSublotDeleted** check), **Sublot deleted (SR0700.3.6.6)** error message (GID-2668487).
	50	If all checks have passed successfully, the container/sublot is identified and its status is set to **Recording**.
	60	**Result (SR0700.9.1)** output variable (GID-2668495)is set to WEIGH and phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.1.3 GID-2669867 OUTPUT WEIGHING DONE (SR0700.2.3)

- Function: Output Weighing is done
- Type: Main path
- Trigger: Operator selects **Done** option button
- Postcondition: Status of the output material is set to a final state and calculations are triggered.

Step	#	Description
Operators selects **Done** option button	10	Phase updates the status of the output material position as follows: ▪ **In tolerance**: produced quantity is within tolerances. ▪ **Overweight**: produced quantity is greater than upper tolerance. ▪ **Underweight**: produced quantity is less than lower tolerance. ▪ **Done**: no planned quantity is maintained. Replaced containers/sublots are not taken into account. The status is not updated if the phase operates in **Prepare only** mode (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
	20	If a planned quantity is maintained, phase calculates and displays ▪ Yield = Actual quantity / Planned quantity (The planned quantity that might be updated.) and ▪ Prorate factor = Actual quantity / Planned quantity (original) Replaced containers/sublots are not taken into account. The values are stored within the **Yield (SR0700.9.2)** output variable (GID-2668496)and the **Prorate factor (SR0700.9.3)** output variable (GID-2668497). Yield and prorate factor are not calculated if the phase operates in **Prepare only** mode (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996). In this case, phase displays "N/A".
	30	If a phase completion signature is assigned, the signature is only requested during execution if the **Done** option button is selected.
	40	If the **Done** option button is selected, upon phase completion, all of the phase-specific data is available within the sub-report, see **Sub-report elements (Done) (SR0700.5.2)** representation (GID-2669864).

Step	#	Description
Operator selects **Continue** option button	100	▪ Phase updates the status of the output material position back to **In process**. ▪ Result of yield and prorate factor calculation is withdrawn. This includes the **Yield (SR0700.9.2)** output variable (GID-2668496)and **Prorate factor (SR0700.9.3)** output variable (GID-2668497). ▪ Phase completion signature (if configured) is removed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.1.4 GID-2669868 CONFIRM BY SCAN (SR0700.2.4)

- Function: Confirm phase by use of barcode scan
- Type: Main path
- Precondition: **Continue** option button is selected
- Trigger: Operator scans any scale
- Postcondition: Phase is completed

Step	#	Description
Operator scans scale	10	If the **Continue** option button is selected, phase sets the **Result (SR0700.9.1)** output variable (GID-2668495)to WEIGH. Phase completion signature (if configured) is ignored. Continue with step 20.2.
	20.1	If the **Done** option button is selected, **Confirm by scan** is not supported and the phase is not completed automatically.
	20.2	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.1.5 GID-2669869 CONFIRM BY BUTTON (SR0700.2.5)

- Function: Confirm phase by use of button
- Type: Main path
- Trigger: Operator confirms phase
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	If the **Continue** option button is selected, phase sets the **Result (SR0700.9.1)** output variable (GID-2668495)to WEIGH. Phase completion signature (if configured) is ignored. Continue with step 50.
	20.1	If the **Done** option button is selected, the following checks apply upon phase completion: ▪ Unless all container/sublot weights are recorded, phase displays the **Weight of sublots missing (SR0700.3.6.4)** error message (GID-2668485). ▪ The check is skipped if the phase operates in **Prepare only** mode (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
	20.2	▪ If the expected number of containers/sublots is violated (sublots in the **Annulled** or **Replaced** status are excluded), phase displays the **Violated number of sublots (SR0700.3.2.1)** system-triggered exception (GID-2669877).
	20.3	▪ If the produced quantity is greater than the upper tolerance, phase displays the **Overweight check (SR0700.3.2.2)** system-triggered exception (GID-2669878). ▪ The check is skipped if the phase operates in **Prepare only** mode (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
	20.4	▪ If the produced quantity is less than the lower tolerance, phase displays the **Underweight check (SR0700.3.2.3)** system-triggered exception (GID-2669879). ▪ The check is skipped if the phase operates in **Prepare only** mode (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
	30	If the **Done** option button is selected, phase completion signature (if configured) becomes active.
	40	If the **Done** option button is selected and all checks are passed successfully (or system-triggered exceptions are recorded), phase sets the **Result (SR0700.9.1)** output variable (GID-2668495)to COMPLETED.

Step	#	Description
	50	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.2 Weighing Method-specific Paths

There are no specifics available for any of the supported weighing methods.

3.2.3 Equipment Management

Business logic related to equipment management:

3.2.3.1 GID-2669870 Container management (SR0700.2.6)

- Function: Manage container
- Type: Special handling of container binding, binding context, and graph transitions
- Precondition: Container must be of the **Container (RS)** equipment type
- Trigger: Empty or prepared target container has been identified during Output Weighing
- Postcondition: Container life cycle is maintained

Step	Description
Case: Return to material management user-triggered exception was performed in a previous phase (after loop). Affected phases: **Select scale** (SR0710+) (GID-2668063), **Identify container** (SR0750+) (GID-2668073), **Tare** (SR0720+) (GID-2668083), **Weigh** (SR0730+) (GID-2668094)	In case container is not yet **Prepared** (not known in the context of the order step output): ▪ Phase sends **CONT_EMPTY** trigger to the graph of the **Container Cleaning (RS)** purpose. In case the container is an equipment group, the trigger is sent to each equipment entity of the equipment group. ▪ Phase resets binding context and unbinds container. In case the container is an equipment group, the unbinding is performed for each equipment entity of the equipment group. In case container is already **Prepared** (i.e. it is still bound): ▪ No trigger is performed. ▪ No unbind is performed.

Step	Description
Case: Annul prepared sublot (SR0700.3.1.3) user-triggered exception (GID-2669887)was performed.	▪ Phase does not only handle prepared sublots, but also prepared container. ▪ Phase does not clear container's property of the **Current Tare (RS)** purpose. ▪ Phase sends **CONT_LOAD** trigger to the graph of the **Container Cleaning (RS)** purpose. In case the container is an equipment group, the trigger is sent to each equipment entity of the equipment group. ▪ Phase resets binding context and unbinds container. In case the container is an equipment group, the unbinding is performed for each equipment entity of the equipment group.
Case: Replace weighed sublot (SR0700.3.1.4) user-triggered exception (GID-2669889)was performed.	▪ Phase also handles replaced sublots that are associated with prepared containers. ▪ No action is performed on the container object. ▪ No bind/unbind is performed (container is already unbound after successful weighing, see **Container management (SR0730.2.10)** function (GID-2670006)of the **Weigh** phase). ▪ Phase does not clear container's properties of the **Current Tare (RS)** or **Current Sublot (RS)** purposes. ▪ No trigger is performed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2.3.2 GID-2669871 SCALE MANAGEMENT (SR0700.2.7)

Does not apply if the **Quantity entry** weighing method is used.

- Function: Manage scales
- Type: Special handling of scale binding and binding context
- Precondition: Scale must be of the **Scale (RS)** equipment type
- Postcondition: Scale life cycle is maintained

Step	Description
Case: Phase is activated	▪ Phase resets binding context and unbinds the scale. ▪ This also applies when the phase is activated after the **Return to material management** user-triggered exception was performed in a previous phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3 Recipe Parameters

The phase provides process parameters (GID-2668474).

3.3.1 Process Parameters (SR0700.8+)

The following process parameters define the behavior of the phase.

3.3.1.1 Instruction Table-specific Parameters

3.3.1.1.1 Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

3.3.1.1.2 Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

3.3.1.2 Instruction Link-specific Parameters

3.3.1.2.1 Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671994). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

3.3.1.2.2 Instruction link definition (Framework capability)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

3.3.1.3 Basic Parameters

3.3.1.3.1 GID-2671995 Instruction (SR0700.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.3.2 GID-2671996 Operation mode (SR0700.8.12)

Attribute	Type	Comment
Mode	Choice list	Defines the operation mode. **Flexible** (default): Allows to prepare and to weigh containers or sublots. **Prepare only**: Only allows to prepare containers or sublots. They can neither be identified nor weighed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.3.3 GID-2671997 Prorate factor (SR0700.8.6)

Attribute	Type	Comment
Value	MeasuredValue	Prorate factor to be applied. It is only applied once automatically, i.e. not in case of resume, reactivation, or within a loop.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.3.4 GID-2671998 NUMBER OF SUBLOTS (SR0700.8.2)

Attribute	Type	Comment
Minimum	Long	Defines the minimum number of containers or sublots.
Maximum	Long	Defines the maximum number of containers or sublots.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.4 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

3.3.1.4.1 GID-2671999 NUMBER OF SUBLOTS CHECK (SR0700.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Violated number of sublots (SR0700.3.2.1)** system-triggered exception (GID-2669877).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.4.2 GID-2672000 CONFIRM OVERWEIGHT (SR0700.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Overweight check (SR0700.3.2.2)** system-triggered exception (GID-2669878).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.4.3 GID-2672001 CONFIRM UNDERWEIGHT (SR0700.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Underweight check (SR0700.3.2.3)** system-triggered exception (GID-2669879).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.4.4 GID-2672002 STATUS TRANSITION FAILED (SR0700.8.13)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Status transition failed (SR0700.3.2.5)** system-triggered exception (GID-2669881).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.5 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

3.3.1.5.1 GID-2672141 OVERRIDE PRORATE FACTOR (SR0700.8.9)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override prorate factor (SR0700.3.1.1)** user-triggered exception (GID-2669883).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.5.2 GID-2672003 IDENTIFY MANUALLY (SR0700.8.10)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Identify manually (SR0700.3.1.2)** user-triggered exception (GID-2669885).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.5.3 GID-2672004 ANNUL PREPARED SUBLOT (SR0700.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Annul prepared sublot (SR0700.3.1.1)** user-triggered exception (GID-2669883).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.1.5.4 GID-2672005 REPLACE WEIGHED SUBLOT (SR0700.8.11)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Replace weighed sublot (SR0700.3.1.4)** user-triggered exception (GID-2669889).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.4 Exceptions (SR0700.3+)

(GID-2668477)The phase supports user-defined, user-triggered (GID-2668476), system-triggered (GID-2668475), and post-completion exceptions link and their configuration by means of process parameters (GID-2668474).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

3.4.1 System-triggered Exceptions (SR0700.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

3.4.1.1 GID-2669877 VIOLATED NUMBER OF SUBLOTS (SR0700.3.2.1)

After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

- <Exception text>
  (taken from **Number of sublots check (SR0700.8.4)** process parameter (GID-2671999))
  Batch: <batch identifier>, material: <material identifier>
  Expected number of containers/sublots: [<value> .. <value>]
  Actual value: <value>
  - Example:
    Expected number of container/sublots violated.
    Batch: BX123, material: D-9001-03
    Expected number of containers/sublots: [15 .. 18]
    Actual value: 19

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.2 GID-2669878 OVERWEIGHT CHECK (SR0700.3.2.2)

After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

- <Exception text>
  (taken from **Confirm overweight (SR0700.8.7)** process parameter (GID-2672000))
  Batch: <batch identifier>, material: <material identifier>
  Expected tolerances: [<lower limit> .. <upper limit>]
  Actual value: <value>
  - Example:
    Overweight situation.
    Batch: BX123, material: D-9001-03
    Expected tolerances: [100 kg .. 150 kg]
    Actual value: 154 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.3 GID-2669879 UNDERWEIGHT CHECK (SR0700.3.2.3)

After the exception has been recorded, the phase is automatically completed.

Representation of the exception:

- <Exception text>
  (taken from **Confirm underweight (SR0700.8.8)** process parameter (GID-2672001))
  Batch: <batch identifier>, material: <material identifier>
  Expected tolerances: [<lower limit> .. <upper limit>]
  Actual value: <value>
  - Example:
    Underweight situation.
    Batch: BX123, material: D-9001-3
    Expected tolerances: [100 kg .. 150 kg]
    Actual value: 85 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.4 GID-2669880 MULTIPLE EXCEPTIONS (SR0700.3.2.4)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.5 GID-2669881 STATUS TRANSITION FAILED (SR0700.3.2.5)

The **Status transition failed** exception is displayed automatically if a certain status transition could not be performed based on the given graph purpose and trigger.

In case the trigger was executed on a container and the container is an equipment group, multiple failed transitions on different entities can be reported combined in one exception.

The potential reasons for a failed status transition are:

- The graph of the required purpose is missing.
- The trigger is missing.
- Source status does not match.
- Condition cannot be fulfilled or is not unique (in case of multiple transition definitions per trigger).
- Error during condition evaluation.
- Error during action evaluation.

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Status transition failed (SR0700.8.13)** process parameter (GID-2672002))
  <the reason that applies>
- List of potential reasons:
  - The graph of the required purpose is missing.
  - The trigger you are trying to perform is not contained in the graph.
  - Cannot find a transition for the current status.
  - Cannot find a fulfillable transition condition for the current status.
  - There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.
  - Cannot evaluate the transition condition (<TR-ID>).
  - Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

Exception Window

- <Exception text>
  (taken from **Status transition failed (SR0700.8.13)** process parameter (GID-2672002))
  <reason>
  Equipment: <equipment identifier> / <equipment short description>
  Equipment type: <list of equipment types> (if available)
  Graph (ID): <graph display text> (<identifier>)
  Purpose: <purpose>
  Current status (key): <display text> (<key>)
  Failed trigger (key): <display text> (<key>)
  - Example:
    Status transition failed.
    Cannot find a transition for the current status.
    Equipment: IBC0033
    Equipment type: Container (RS)
    Graph (ID): IBC Cleaning (IBCCleaning01)
    Purpose: Container Cleaning (RS)
    Current status (key): Blocked (BLOCKED)
    Failed trigger (key): In use (IN_USE)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.1.6 GID-2669882 STATUS TRANSITION FAILED - LOGIC (SR0700.3.2.5.1)

- Trigger: The status transition could not be performed based on the given graph purpose and trigger.
- Postcondition: Phase is active

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2 User-triggered Exceptions (SR0700.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

3.4.2.1 GID-2669883 Override prorate factor (SR0700.3.1.1)

The **Override prorate factor** exception allows an operator to override the prorate factor and apply a new prorate factor.

Representation of the exception:

- Instruction:
  Override the prorate factor with a new value.
  Box for new prorate factor.
  Confirm button.
- Exception text
  <Exception text>
  (taken from **Override prorate factor (SR0700.8.9)** process parameter (GID-2672141))
  Original prorate factor: <value>
  New prorate factor: <value>
  - Example:
    Prorate factor overridden and applied.
    Original prorate factor 0.88
    New prorate factor: 0.92

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.2 GID-2669884 Override prorate factor - Logic (SR0700.3.1.1.1)

- Trigger: Exception is selected
- Precondition: **Continue** option button is selected
- Postcondition: New prorate factor is applied and exception is recorded

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.

Step	#	Description
Operator confirms exception	20	Phase applies new prorate factor, which means the planned quantity is updated (= original quantity * prorate factor), and records exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.3 GID-2669885 IDENTIFY MANUALLY (SR0700.3.1.2)

The **Identify manually** exception allows an operator to identify a container/sublot manually.

The exception is disabled if the phase's **Operation mode** is set to **Prepare only**.

Representation during exception handling:

- Instruction:
  Enter the container or sublot you wish to identify.
  Box for barcode input.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Identify manually (SR0700.8.10)** process parameter (GID-2672003))
  Identified container/sublot: <container/sublot identifier>
  - Example:
    Manual identification.
    Identified container/sublot: SL00005678

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.4 GID-2669886 IDENTIFY MANUALLY - LOGIC (SR0700.3.1.2.1)

- Trigger: Exception is selected
- Precondition: Phase's **Operation mode** is not set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
- Postcondition: Phase is completed

Step	#	Description
Operator confirms exception	10	Phase performs checks as listed for the **Sublot barcode scan (SR0700.2.2)** function (GID-2669866).
	20	If all checks have passed successfully, phase records the exception according to the **Identify manually (SR0700.8.10)** process parameter (GID-2672003).
	25	In case the identifier of a prepared container/sublot has been entered, but the container/sublot has already been identified at another client, phase displays the **Wrong container/sublot status (SR0700.3.6.9)** error message (GID-2668490)when the operator signs the exception.
	30	Container/sublot is identified and phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.5 GID-2669887 ANNUL PREPARED SUBLOT (SR0700.3.1.3)

The **Annul prepared sublot** exception allows an operator to annul one or all of the already prepared containers/sublots.

Representation during exception handling:

- Instruction:
  Scan or type the container or sublot you wish to annul.
  Box for barcode input.
  List of prepared containers/sublots.
  Single option button (default) and **All** option button.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Annul prepared sublot (SR0700.8.5)** process parameter (GID-2672004))
  If one container/sublot was annulled:
  <Material identifier> / <Material short description> / <Batch identifier> / <Container/sublot identifier>
  If all containers/sublots were annulled:
  <Material identifier> / <Material short description> / <Batch identifier> / <Container/sublot identifiers, comma-separated list>

- Example (one sublot was annulled):
  Container/sublot annulled.
  D001-03 / Aqua purificata / BX123 / SL00001234

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.6 GID-2669888 ANNUL PREPARED SUBLOT - LOGIC (SR0700.3.1.3.1)

- Trigger: Exception is selected
- Precondition: Container/sublot must be in the **Prepared** status.
- Postcondition: Container/sublot is annulled and can no longer be identified for weighing as an output material container/sublot.

Step	#	Description
Operator selects **Single** option button and confirms exception	10	Phase checks if the container/sublot to be annulled is available in the list of prepared containers/sublots of this order step. If not, phase displays the **Sublot is not prepared or cannot be replaced (SR0700.3.6.2)** error message (GID-2668483)or the **Container not prepared or recorded for this order step output (SR0700.3.6.10)** error message (GID-2668489).
	15	In case a container/sublot is still displayed with its **Prepared** status, but the container/sublot has already been annulled or its weight has already been recorded at another client, phase displays the **Wrong container/sublot status (SR0700.3.6.9)** error message (GID-2668490).
	20	If the check passes successfully, phase annuls the container/sublot and records the exception according to the **Annul prepared sublot (SR0700.8.5)** process parameter (GID-2672004).
Operator selects **All** option button and confirms exception	30	Phase does not allow to define a single container/sublot to be annulled. Upon confirmation, all remaining prepared container/sublots are annulled and phase records the exception according to the **Annul prepared sublot (SR0700.8.5)** process parameter (GID-2672004).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.7 GID-2669889 Replace weighed sublot (SR0700.3.1.4)

The **Replace weighed sublot** exception allows an operator to replace one of the already weighed container/sublots.

The exception is disabled if the phase's **Operation mode** is set to **Prepare only**.

Representation during exception handling:

- Instruction:
  Scan or type the container or sublot you wish to replace.
  Box for barcode input.
  List of recorded containers/sublots.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Replace weighed sublot (SR0700.8.11)** process parameter (GID-2672005))
  <Material identifier> / <Material short description> / <Batch identifier> / <Container/sublot identifier>
  - Example:
    Container/sublot replaced after weighing.
    D001-03 / Aqua purificata / BX123 / SL00001234

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.2.8 GID-2669890 Replace weighed sublot - Logic (SR0700.3.1.4.1)

- Trigger: Exception is selected
- Precondition: Phase's **Operation mode** is not set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
- Postcondition: Container/sublot is replaced and can no longer be identified as an intra material within the succeeding unit procedure.

Step	#	Description
Operator confirms exception	10	Phase checks if the container/sublot to be replaced is available in the list of recorded containers/sublots of this order step. If not, phase displays the **Sublot is not prepared or cannot be replaced (SR0700.3.6.2)** error message (GID-2668483)or the **Container not prepared or recorded for this order step output (SR0700.3.6.10)** error message (GID-2668489).

Step	#	Description
	15	In case a container/sublot is still displayed with its **Recorded** status, but the container/sublot has already been replaced at another client, phase displays the **Wrong container/sublot status (SR0700.3.6.9)** error message (GID-2668490).
	20	If the check passes successfully, phase marks the sublot as replaced and updates the produced and remaining quantity of the output material position accordingly. Phase records the exception according to the **Replace weighed sublot (SR0700.8.11)** process parameter (GID-2672005).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

3.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

3.5 Information Messages (SR0700.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

3.5.1 GID-2668478 Invalid prorate factor (SR0700.3.4.1)

UI text	Comment
The prorate factor has an invalid value (<value>). The related planned quantities have been set to zero. Apply a correct prorate factor manually.	Message pack: ow_ManProdMat<version> Message ID: OverrideProrateFactorInvalidValue

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.5.2 GID-2668479 No sublot available to annul (SR0700.3.4.3)

UI text	Comment
There are no prepared containers or sublots available to annul.	Message pack: ow_ManProdMat<version> Message ID: noItemsToAnull_InfoMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.6 Questions

There are no questions available.

3.7 Decisions

There are no decisions available.

3.8 Error Messages (SR0700.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

3.8.1 GID-2668480 Invalid barcode (SR0700.3.6.1)

UI text	Comment
The scanned barcode does not belong to a container or sublot.	Message pack: wd_UIMessage<version> Message ID: NoContainerOrSublotScanned_ErrorMsg Applies if the scanned barcode presents neither a container nor a sublot.
The barcode (<barcode>) does not match the required barcode format. Please scan again or identify manually.	Message pack: clientfw_pec.BarcodeScannerSupport Message ID: no_matching_templates_1 Applies if the scanned barcode starts with a sublot prefix, but is too short.

UI text	Comment
The barcode (<barcode>) does not contain all information required to identify a sublot. Please scan again or identify manually.	Message pack: clientfw_pec.BarcodeScannerSupport Message ID: not_enough_information_for_sublot Applies in case system is configured to require separate scans of sublot and batch at sublot identification.
The barcodes (<barcode>) do not match the required barcode format. Please scan again or identify manually.	Message pack: clientfw_pec.BarcodeScannerSupport Message ID: no_matching_templates_n Applies in case system is configured to require separate scans of sublot and batch at sublot identification.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.2 GID-2668481 Sublot identifier missing (SR0700.3.6.11)

UI text	Comment
Please enter a container or sublot ID.	Message pack: ow_ManProdMat<version> Message ID: noDataForIdentification

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.3 GID-2668482 Prepare only (SR0700.3.6.7)

UI text	Comment
Cannot identify a container or sublot, since the phase's mode only allows preparation.	Message pack: ow_ManProdMat<version> Message ID: noIdentificationInPrepareOnly_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.4 GID-2668483 Sublot is not prepared or cannot be replaced (SR0700.3.6.2)

UI text	Comment
Cannot proceed with the <sublot ID> sublot, since its status (<status>) is unsuitable. For identification, the sublot needs to be in the <status> status.	Sublot must be in the **Prepared** status to be scanned for weighing. Sublot must be in the **Prepared** status to be annulled. Sublot must be in the **Recorded** status to be replaced. Message pack: srv_wd.checks Message ID: CheckSublotOutputStatus_0
Cannot proceed with the <sublot ID> sublot, since it has no status.	Message pack: srv_wd.checks Message ID: CheckSublotOutputStatus_1

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.5 GID-2668484 Sublot does not exist (SR0700.3.6.3)

UI text	Comment
Cannot find a sublot to match the barcode (<barcode>).	Identification by scanner: Message pack: clientfw_pec.BarcodeScannerSupport Message ID: no_sublot_found_1
Cannot find the container or sublot ID. Please correct your input.	Manual identification: Message pack: ow_ManProdMat<version> Message ID: sublotNotFound_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.6 GID-2668485 Weight of sublots missing (SR0700.3.6.4)

UI text	Comment
Cannot complete the phase, since there are one or more prepared containers or sublots that have not been weighed yet.	Check only applies if the **Done** option button is selected. Message pack: ow_ManProdMat<version> Message ID: weightOfItemsMissing_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.7 GID-2668486 Sublot for different order step output (SR0700.3.6.5)

UI text	Comment
The sublot (<sublot ID>) was not prepared for the order step output of this order step.	Message pack: srv_wd.checks Message ID: CheckSublotIsProducedForOSO_0

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.8 GID-2668487 Sublot deleted (SR0700.3.6.6)

UI text	Comment
The sublot (<sublot ID) has already been consumed.	Message pack: srv_wd.checks Message ID: CheckSublotDeleted_0

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.9 GID-2668488 No sublot identification (SR0700.3.6.8)

UI text	Comment
Cannot identify a container or sublot, since you have the Done option selected. Select Continue to proceed with identification.	Message pack: ow_ManProdMat<version> Message ID: noIdentificationInDoneMode_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.10 GID-2668489 Container not prepared or recorded for this order step output (SR0700.3.6.10)

UI text	Comment
Cannot proceed with the <container ID> container, since it is not prepared for this order step output.	Message pack: srv_wd.checks Message ID: CheckContainerIsPreparedForOSO
Cannot proceed with the <container ID> container, since it is not recorded for this order step output.	Message pack: srv_wd.checks Message ID: CheckContainerIsRecordedForOSO

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.8.11 GID-2668490 Wrong container/sublot status (SR0700.3.6.9)

UI text	Comment
Cannot identify the container/sublot, since its status has changed in the meantime. To continue processing, return to the Execution Window.	Message pack: ow_ManProdMat<version> Message ID: setSublotOutputStatusRecording_ErrorMsg

UI text	Comment
Cannot annul the container(s)/sublot(s), since its/their status has changed in the meantime. To continue processing, return to the Execution Window.	Message pack: ow_ManProdMat<version> Message ID: annulPreparedItems_ErrorMsg
Cannot replace the container/sublot, since its status has changed in the meantime. To continue processing, return to the Execution Window.	Message pack: ow_ManProdMat<version> Message ID: replaceRecordedSublot_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9 Output Variables (SR0700.9+)

The following output variables are available to reference the phase's output.

3.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

3.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

3.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

3.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

3.9.5 GID-2668495 Result (SR0700.9.1)

- Data type: String
- Values: WEIGH, COMPLETED
- Usage: The output variable provides the result of the phase processing:
- The value is WEIGH if there is output material for processing in the Output Weighing loop.
- The value is COMPLETED if there is no material left for processing.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.6 GID-2668496 Yield (SR0700.9.2)

- Data type: MeasuredValue
- Usage: The output variable provides the calculated yield as **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.9.7 GID-2668497 Prorate factor (SR0700.9.3)

- Data type: MeasuredValue
- Usage: The output variable provides the calculated prorate factor as **MeasuredValue** object.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4 Select Scale Phase (SR0710+)

The **Select scale** phase (O Select Scale) allows an operator to select a weighing method and an appropriate scale. Upon phase completion, the connected scale is initialized and zeroed.

It can provide to up to five scales for selection that are connected to a work center. If more scales are used that are dedicated to a specific work center, the respective phase capabilities need to be adapted. In addition to pre-assigned scales, scales that are not assigned to this specific work center can also be used (shared scales).
The **Select scale** phase pre-selects the default weighing method defined with the material identified for processing, but also lets an operator switch manually to any other weighing method allowed in the material's parameters and supported for Output Weighing. The phase collects the tolerance and resolution data of all scales configured for a work center, matches it against the target load requirements of the identified material, and pre-selects the scale that is best suited to perform the task. It prevents scales that are not sufficiently tested or calibrated from being used. An operator can select another scale manually, provided it meets the tolerance and scale resolution requirements of the material to be processed. The operator confirms the scale to be used by scanning the barcode of the scale.
If the **Quantity entry** weighing method is selected, no scale can be selected.
Details of the selected scale and weighing method are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report.
Anomalies that occur during processing are covered by the phase exception handling (e.g. using an offline scale).
After completion the phase displays the selected weighing method and scale, both in the Execution Window and in the Navigator.

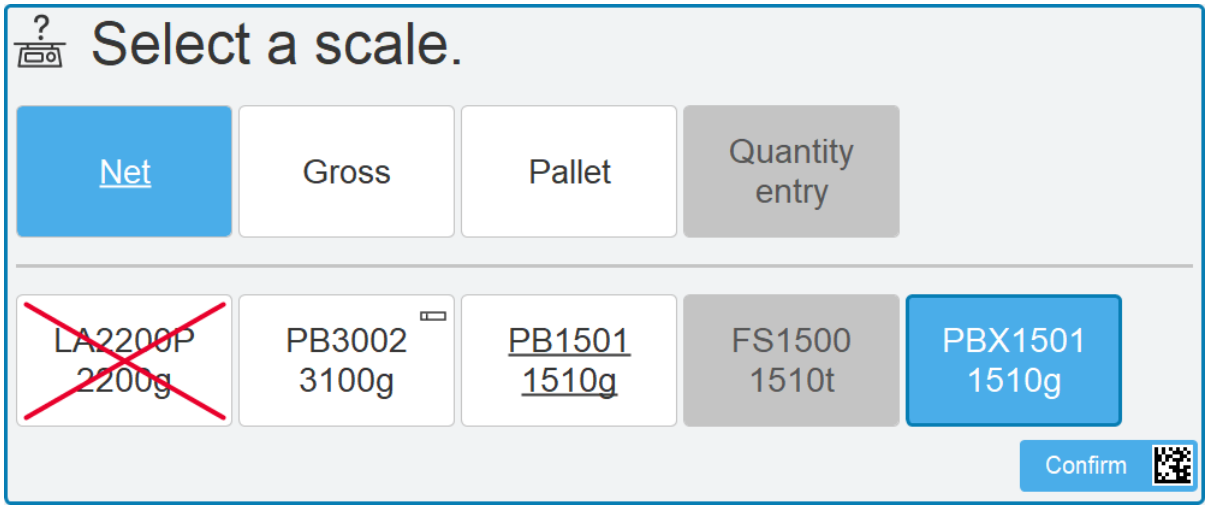

Figure 11: Select scale during execution

4.1 Layout

The phase provides individual layouts for its representation during execution (GID-2668498), in the Navigator (GID-2668499), and in the sub-report (GID-2668500).

4.1.1 Representation during Execution (SR0710.1+)

The representation during execution depends on the phase mode.

4.1.1.1 GID-2669891 Preview mode (SR0710.1.1)

1. Phase-specific icon.
2. <Instruction text>
   (taken from **Instruction (SR0710.8.1)** process parameter (GID-2672010))
3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.2 GID-2669892 Active mode (SR0710.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0710.8.1)** process parameter (GID-2672010))
4. List of weighing methods available for selection
   (taken from material output parameter of the Weigh phase (SR0730.7.1) (GID-2670008))
   In case a sublot with known tare has been identified (weighing of a prepared and loaded sublot), only the **Net weighing** and **Quantity entry** weighing methods are available for selection.
   In case the prepared sublot does not have a known tare since the **Quantity entry** weighing method was used for the preparation, the **Quantity entry** weighing method is automatically selected and the phase is automatically completed.

Content	UI text	Comment
Net weighing	Net	---

Content	UI text	Comment
Gross weighing	Gross	Not available if the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
Pallet weighing	Pallet	Not available if the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
Quantity entry	Quantity entry	If selected, cell background of scales is changed to gray. No scale can be selected.
<empty>	---	---

5. List of scales available for selection, depends on work center data, scale-related weighing range, test status, and calibration status.

Content	UI text	Comment
Connected scale (1)	<Short description>	Phase displays scale identifier if short description is not available.
Connected scale (2)	<Short description>	Phase displays scale identifier if short description is not available.
...	...	...

LEGEND
Weight icon: scale is marked as loaded.
Input box icon: scale is configured as manual scale
Underlined text: item was suggested by phase (best scale or default weighing method).
Blue background and bold blue border: item is selected.
White background: item is selectable.
Gray background: item is not selectable.
Red cross: Item is not usable due to missing scale test and/or calibration

6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.3 GID-2669893 COMPLETED MODE (SR0710.1.3)

7. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
8. Phase-specific icon.
9. <Selected weighing method>
10. <Identifier of selected scale>
11. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2 Representation in Navigator (SR0710.4+)

The Navigator provides the following details:

4.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:
    Select Scale

4.1.2.2 GID-2669895 INFORMATION COLUMN (SR0710.4.1)

- <Selected weighing method> / <identifier of selected scale>
  - For the **Quantity entry** weighing method, phase displays no scale identifier.
    - Example:
      Net / QC7DCES
      Quantity entry

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2.3 ACTION COLUMN

- There are no actions available.

4.1.3 Representation in Sub-report (SR0710.5+)

The sub-report contains the following information:

4.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

4.1.3.2 GID-2669898 SUB-REPORT ELEMENTS (SR0710.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Position: <number>
- Method: <weighing method>
- Selected scale: <scale identifier>
- For the **Quantity entry** weighing method, phase displays "N/A".
- Work center: <work center identifier>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2 Business Logic (SR0710.2+)

The phase implements the following business logic.

4.2.1 Main Path

Business logic related to the main path:

4.2.1.1 GID-2669899 AUTOMATED SCALE SELECTION (SR0710.2.1)

- Function: Select scale automatically
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: Phase suggests scale

Step	#	Description
Phase activation	10.1	▪ Does not apply if the **Quantity entry** weighing method is the default weighing method. If a planned quantity with its tolerances or a target weight with its tolerances is defined: Phase suggests the most appropriate scale based on tolerances compared to ranges of available scales. In case both planned quantity and target weight are defined with their tolerances, the algorithm uses the smaller tolerance band. The following algorithm is applied: In a first step, phase determines all (0-n) available scales and marks them as "available" in the **Active mode (SR0710.1.2)** layout (GID-2669892). ▪ Criterion 1: If the nominal quantity is outside of the weighing range of the scale, the maximum allowed nominal tolerance band for weighing must be equal or greater than twice the scale resolution ("nominal tolerance" means: based on the nominal quantity (calculated after identification)). Example: Nominal quantity = 10g, lower tolerance = 8g, upper tolerance = 12g, tolerance band = 4g. In this case, scales with a resolution coarser than 2g are not considered. ▪ Criterion 2: If the nominal quantity is within the weighing range of a scale, the tolerances calculated based on the nominal quantity have to meet the following condition: Lower tolerance <= Upper tolerance with Lower tolerance = round up according to the scale resolution (nominal – lower tolerance value (recipe) + scale resolution) Upper tolerance = round down according to the scale resolution (nominal + upper tolerance value (recipe) – scale resolution) ▪ In case of multi-range scales, the system uses the lowest range when checking criteria 1 or 2, assuming it has the best resolution. In a second step, phase determines the suggested (0-1) scale and marks it as "suggested" and initially as "selected" in the **Active mode (SR0710.1.2)** layout (GID-2669892). ▪ Criterion 3: If multiple scales fulfill criterion 1, the scale with the coarsest resolution will be suggested.
	10.2	▪ Does not apply if the **Quantity entry** weighing method is the default weighing method. If no planned quantity or target weight with tolerances is defined: ▪ Phase suggests the most appropriate scale with the coarsest resolution.

Step	#	Description
	50	Phase determines test and calibration statuses of all scales and also checks if test or calibration statuses are expired (simulation).
	60	Phase marks not tested or not calibrated scales as "not ready" in the **Active mode (SR0710.1.2)** layout (GID-2669892).
	70	Phase marks neither "suggested" nor "available" scales as "not available" in the **Active mode (SR0710.1.2)** layout (GID-2669892).
	80	▪ Does not apply if the **Quantity entry** weighing method is the default weighing method. In case a scale's property of the **Current Load (RS)** purpose is not empty, phase marks the scale as loaded.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.2 GID-2669900 AUTOMATED WM SELECTION (SR0710.2.2)

- Function: Select weighing method automatically
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: Phase suggests weighing method

Step	#	Description
Phase activation	10	Phase suggests appropriate weighing method based on the default weighing method of the related material parameter. (**Net removal** weighing is not supported for Output Weighing.) In case a sublot with known tare has been identified (weighing of a prepared and loaded sublot), phase selects the **Net** weighing method.
	20	Phase marks weighing method as "suggested" and "available" in the **Active mode (SR0710.1.2)** layout (GID-2669892).
	25	If **Quantity entry** is the default weighing method, the cell background of scales is changed to gray. No scale can be selected.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.3 GID-2669901 MANUAL SCALE SELECTION (SR0710.2.3)

Does not apply if the **Quantity entry** weighing method is used.

- Function: Select scale manually
- Type: Main path
- Trigger: Operator selects scale manually.
  Available scales are marked by **Automated scale selection (SR0710.2.1)** function (GID-2669899).
- Postcondition: Selected scale

Step	#	Description
Operator selects scale	10	Phase marks selected scale as selected in the **Active mode (SR0710.1.2)** layout (GID-2669892).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.4 GID-2669902 MANUAL SCALE SELECTION BY SCAN (SR0710.2.4)

Does not apply if the **Quantity entry** weighing method is used.

- Function: Select scale manually by use of barcode scan
- Type: Main path
- Trigger: Operator scans scale
  Available scales are marked by **Automated scale selection (SR0710.2.1)** function (GID-2669899). Phase also allows to scan shared scales that are not assigned to the current work center.
- Postcondition: Selected scale

Step	#	Description
Operator scans scale	5	Phase reads scanned data.
	10	▪ If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading. ▪ If barcode reading was technically not successful, phase remains in listening mode.

Step	#	Description
	12	▪ If, for the scale that has been marked as "selected", no barcode is maintained in the basic data of the scale equipment entity, phase displays the **Inventory number missing (SR0710.3.6.4)** error message (GID-2668512). ▪ If the scanned barcode does not belong to a scale, phase displays the **Barcode not valid (SR0710.3.6.1)** error message (GID-2668509).
	15	In case the **Allow use of shared scales (SR0710.8.5)** process parameter (GID-2672011)is set to **Yes** and the barcode does not correspond to any of the suggested or available scales, phase adds the scanned scale to the list of scales, in addition to the already listed scales. The shared scale is selected. If another shared scale is scanned, the new scale will replace the previous shared scale. Another scan is necessary to trigger the **Manual scale selection by scan (SR0710.2.4)** function.
	15.1	If the shared scale cannot be used for the material position (see checks of the **Automated scale selection (SR0710.2.1)** function (GID-2669899)), phase displays the **Scale is not suitable (SR0710.3.6.8)** error message (GID-2668516).
	20	In case the **Allow use of shared scales (SR0710.8.5)** process parameter (GID-2672011)is set to **No** and the barcode does not correspond to any of the suggested or available scales, phase displays the **Scale not listed (SR0710.3.6.6)** error message (GID-2668514)
	30	If barcode represents an available scale, phase marks new scale as selected in the **Active mode (SR0710.1.2)** layout (GID-2669892). Another scan is necessary to trigger **Manual scale selection by scan (SR0710.2.4)** again.
Phase checks expiry status of graphs	35	If barcode represents the selected scale, the **Refresh expired equipment status (SR0710.2.7)** function (GID-2669905)becomes active.
Phase checks if scale is loaded	36	If the selected scale's property of the **Current Load (RS)** purpose is not empty, the **Confirm scale load (SR0710.2.8)** function (GID-2669906)becomes active.
	38	The selected scale is bound and its binding context is set.

Step	#	Description
	39	If the scale's property of the **Current Load (RS)** purpose is not empty and the scale load has been confirmed successfully, zeroing is skipped and the phase is completed automatically. If the scale's property of the **Current Load (RS)** purpose is empty, continue with step 40.
	40	Phase zeros the scale and is completed automatically. Zeroing is only executed if ▪ the **Zeroing** option is selected in the equipment master data of the current scale and ▪ the selected scale is not configured as manual scale.
	45	If barcode represents a scale marked as "not ready", phase displays the **Scale status error (SR0710.3.6.3)** error message (GID-2668511).
	50	If the phase tries to zero the scale, but zeroing fails, phase displays the **Scale driver error (SR0710.3.6.7)** error message (GID-2668515).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.5 GID-2669903 MANUAL WM SELECTION (SR0710.2.5)

- Function: Select weighing method manually
- Type: Main path
- Trigger: Operator selects weighing method manually
- Postcondition: Selected weighing method

Step	#	Description
Operator selects weighing method	10	Phase marks selected weighing method as selected in the **Active mode (SR0710.1.2)** layout (GID-2669892). If **Quantity entry** is the selected weighing method, the cell background of scales is changed to gray. No scale can be selected.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.6 GID-2669904 MANUAL CONFIRMATION (SR0710.2.6)

- Function: Confirm phase manually
- Type: Main path
- Trigger: Operator confirms phase
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	If **Quantity entry** is the selected weighing method, continue with step 30. If selected scale is marked as "not ready", phase displays the **Scale status error (SR0710.3.6.3)** error message (GID-2668511).
Phase checks expiry status of graphs	15	The **Refresh expired equipment status (SR0710.2.7)** function (GID-2669905)becomes active.
Phase checks if scale is loaded	16	If the selected scale's property of the **Current Load (RS)** purpose is not empty, the **Confirm scale load (SR0710.2.8)** function (GID-2669906)becomes active.
	18	The selected scale is bound and its binding context is set.
	19	If the scale's property of the **Current Load (RS)** purpose is not empty and the scale load has been confirmed successfully, zeroing is skipped and the phase is completed automatically. If the scale's property of the **Current Load (RS)** purpose is empty, continue with step 20.
	20	▪ Does not apply if scale is configured as manual scale. Phase zeros scale. If scale cannot be zeroed, phase displays the **Scale driver error (SR0710.3.6.7)** error message (GID-2668515). If scale cannot be zeroed and scale is offline, phase displays the **Scale communication issue (SR0710.3.5.1)** question (GID-2668508). Zeroing is only executed if the **Zeroing** option is selected in the equipment master data of the current scale.
	30	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.7 GID-2669905 REFRESH EXPIRED EQUIPMENT STATUS (SR0710.2.7)

- Function: Refresh the expired statuses of an equipment entity
- Type: Main path
- Trigger: Equipment entity is identified successfully
- Postcondition: Expired equipment graph statuses of entity are updated

Step	#	Description
Phase checks if graph statuses are expired	10	Phase checks in a loop for all equipment graphs assigned to the entity if the current status of equipment graph has expired. ▪ If the status is **not expired**, phase checks the next equipment graph. ▪ If the status is **expired**, phase performs the **Expired (RS)** equipment graph trigger and checks the next equipment graph.
	20	If the execution of any **Expired (RS)** equipment graph trigger fails, phase resets the status of the equipment entity to **Available**, updates the logbook accordingly (if maintained), and displays the **Expired trigger execution failed (SR0710.3.6.9)** error message (GID-2668517).
	30	If the execution of all **Expired (RS)** equipment graph trigger passed successfully, the phase continues with the **Manual scale selection by scan (SR0710.2.4)** function (GID-2669902)or the **Manual confirmation (SR0710.2.6)** function (GID-2669904).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.8 GID-2669906 CONFIRM SCALE LOAD (SR0710.2.8)

- Function: Confirm the scale load
- Type: Main path
- Trigger: Loaded scale is selected
- Postcondition: Loaded scale can be used

Step	#	Description
Phase checks if scale is loaded	10	Phase displays the **Confirm scale load (SR0710.3.4.1)** information message (GID-2668507). If the information message is confirmed without scanning the scale's load, phase displays the **Unsuccessful scan (SR0710.3.6.11)** error message (GID-2668519).

Step	#	Description
	20	Phase checks the scanned container/sublot identifier against the scale's property of the **Current Load (RS)** purpose.
	30	If the check fails, phase displays the **Current load does not match (SR0710.3.6.10)** error message (GID-2668518). A different scale needs to be selected in order to proceed with weighing.
	35	If the check passes successfully, phase continues with the **Manual scale selection by scan (SR0710.2.4)** function (GID-2669902)or the **Manual confirmation (SR0710.2.6)** function (GID-2669904).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.2 Weighing Method-specific Paths

There are no specifics available for any of the supported weighing methods.

4.3 Recipe Parameters

The phase provides process parameters (GID-2668503).

4.3.1 Process Parameters (SR0710.8+)

The following process parameters define the behavior of the phase.

4.3.1.1 Instruction Table-specific Parameters

4.3.1.1.1 Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

4.3.1.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

4.3.1.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

4.3.1.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2672006). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

4.3.1.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.

Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

4.3.1.3 BASIC PARAMETERS

4.3.1.3.1 GID-2672010 INSTRUCTION (SR0710.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.1.3.2 GID-2672011 ALLOW USE OF SHARED SCALES (SR0710.8.5)

Does not apply if the **Quantity entry** weighing method is used.

Attribute	Type	Comment
Enabled	Boolean	Controls if it is allowed to use scales that are not assigned to the current work center.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.1.4 Configuration of User-triggered Exceptions

4.3.1.4.1 GID-2672012 Return to material management (SR0710.8.2)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Return to material management (SR0710.3.1.1)** user-triggered exception (GID-2669911).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.1.4.2 GID-2672013 Select offline scale (SR0710.8.3)

Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Select offline scale (SR0710.3.1.2)** user-triggered exception (GID-2669913).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.1.4.3 GID-2672014 CONFIRM SCALE LOAD MANUALLY (SR0710.8.6)

Does not apply if the **Quantity entry** weighing method is used.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Confirm scale load manually (SR0710.3.1.3)** user-triggered exception (GID-2669915)..

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4 Exceptions (SR0710.3+)

The phase supports user-defined, user-triggered (GID-2668505), system-triggered (GID-2668504), and post-completion exceptions (GID-2668506)and their configuration by means of process parameters (GID-2668503).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

4.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

4.4.2 User-triggered Exceptions (SR0710.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

4.4.2.1 GID-2669911 Return to material management (SR0710.3.1.1)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.

Representation during exception handling:

- Instruction:
  Return to material management.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Return to material management (SR0710.8.2)** process parameter (GID-2672012))
  - Back to material management.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2.2 GID-2669912 RETURN TO MATERIAL MANAGEMENT - LOGIC (SR0710.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator confirms exception	10	Phase records the exception.
	20	Phase is completed automatically and returns to **Manage produced material (SR0700+)** phase (GID-2668053).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2.3 GID-2669913 SELECT OFFLINE SCALE (SR0710.3.1.2)

Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

The **Select offline scale** exception allows an operator to select a scale even though it cannot communicate with the system.

Representation during exception handling:

- Instruction:
  Confirm the use and zeroing of the offline scale.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Select offline scale (SR0710.8.3)** process parameter (GID-2672013)
  - Offline scale selected.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2.4 GID-2669914 SELECT OFFLINE SCALE - LOGIC (SR0710.3.1.2.1)

Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator confirms and adds exception	10	Phase records the exception.
	20	Phase is ready for completion.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2.5 GID-2669915 CONFIRM SCALE LOAD MANUALLY (SR0710.3.1.3)

Does not apply if the **Quantity entry** weighing method is used.

The **Confirm scale load manually** exception allows an operator to confirm the scale load (container/sublot) manually.

The exception is disabled if no loaded scale is selected.

Representation during exception handling:

- Instruction:
  Confirm the scale load manually.
  Box for barcode input.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Confirm scale load manually (SR0710.8.6)** process parameter (GID-2672014))
  Loaded scale: <scale identifier>
  Confirmed scale load (container/sublot): <container/sublot identifier>
  - Example:
    Load confirmed manually.
    Loaded scale: Sc4711Floor
    Confirmed scale load (container/sublot): C00005678

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.2.6 GID-2669916 CONFIRM SCALE LOAD MANUALLY - LOGIC (SR0710.3.1.3.1)

Does not apply if the **Quantity entry** weighing method is used.

- Trigger: Exception is selected
- Precondition: The scale's property of the **Current Load (RS)** purpose is not empty.
- Postcondition: Phase is back in active mode (blocked status, i.e. no other weighing method or scale can be selected).

Step	#	Description
Operator confirms exception	10	Phase checks the entered container/sublot identifier against the scale's property of the **Current Load (RS)** purpose.
	20	If the check fails, phase displays the **Current load does not match (SR0710.3.6.10)** error message (GID-2668518). The exception cannot be signed and completed. A different scale needs to be selected in order to proceed with weighing.
	30	If the check passes successfully, the exception has to be signed.
Operator signs exception	40	Phase returns to active mode. Weighing method or scale selection can no longer be changed. Phase can be completed with the selected scale.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

4.5 Information Messages (SR0710.3.4+)

Information messages are represented in an information dialog containing a message type-specific icon, the information message, and an **OK** button.

The following information messages are available to inform the operator about how to proceed.

4.5.1 GID-2668507 Confirm scale load (SR0710.3.4.1)

UI text	Comment
The scale's load needs to be confirmed. Scan the load's barcode to complete the scale selection.	Message pack: ScaleCurrentLoadChecker<version> Message ID: ConfirmScalesCurrentLoad

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

4.6 Questions (SR0710.3.5+)

Questions are represented in a question dialog containing a message type-specific icon, the question, a **Yes** button, and a **No** button.

The following questions are available to request a decision from the operator how to proceed.

4.6.1 GID-2668508 Scale communication issue (SR0710.3.5.1)

UI text	Comment
A communication error with the selected scale has occurred. The scale has been set to offline mode. Do you wish to reset it to the online mode?	Message pack: wd_UIMessage<version> Message ID: scalesCommunication_QuestionMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.7 Decisions

There are no decisions available.

4.8 Error Messages (SR0710.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

4.8.1 GID-2668509 Barcode not valid (SR0710.3.6.1)

UI text	Comment
This is no valid scale barcode. Please scan a scale to proceed.	Message pack: wd_SelectScale<version> Message ID: invalidBarcode_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.2 GID-2668510 Scale online error (SR0710.3.6.2)

UI text	Comment
A scale communication error has occurred at the <scale> scale.	Message pack: wd_UIMessage<version> Message ID: scalesCommunication_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.3 GID-2668511 Scale status error (SR0710.3.6.3)

UI text	Comment
The status of <scale> is unsuitable. The scale must be calibrated first.	Message pack: wd_SelectScale<version> Message ID: scaleNotCalibrated_ErrorMsg
The status of <scale> is unsuitable. The scale must be tested first.	Message pack: wd_SelectScale<version> Message ID: scaleNotTested_ErrorMsg
The status of <scale> is unsuitable. The scale must be calibrated and tested first.	Message pack: wd_SelectScale<version> Message ID: scaleNotTestedNotCalibrated_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.4 GID-2668512 Inventory number missing (SR0710.3.6.4)

UI text	Comment
The barcode of the <scale> scale is missing. It must be maintained in the basic data of the scale equipment entity.	Message pack: wd_UIMessage<version> Message ID: inventoryNrScaleEmpty_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.5 GID-2668513 Tare above valid range (SR0710.3.6.5)

UI text	Comment
Cannot tare, since the current scale load is above the scale's valid range, which may have been determined by the required scale resolution. Current scale load: <scale load (tare weight)> Your scale load must range between <smallest permitted - minimum> and <highest permitted range - maximum>	Message pack: wd_UIMessage<version> Message ID: scaleNotSuitableForTare_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.6 GID-2668514 Scale not listed (SR0710.3.6.6)

UI text	Comment
The scanned scale is not listed as available. Please select another scale.	Message pack: wd_UIMessage<version> Message ID: noAvailableScalesScanned_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.7 GID-2668515 Scale driver error (SR0710.3.6.7)

UI text	Comment
Cannot obtain a stable reading or a scale communication error has occurred. Please try again.	Message pack: srv_eqm.WDEquipmentService Message ID: zeroFailed

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.8 GID-2668516 Scale is not suitable (SR0710.3.6.8)

UI text	Comment
You have selected a scale that is not suitable for the current material position. Please select another scale.	Message pack: ow_SelectScale<version> Message ID: notAllowedScalesScanned_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.9 GID-2668517 Expired trigger execution failed (SR0710.3.6.9)

UI text	Comment
The <equipment identifier> entity is not suitable, since the update of at least one expired status failed.	Message pack: pec_ExceptionMessage Message ID: cannotIdentifyExpiryTriggerFailure_ErrorMsg The **Details** button provides access to more graph-specific information: <the reason that applies> Equipment: <equipment identifier> / <equipment short description> Equipment type: <list of equipment types> (if available) Graph (ID): <graph display text> (<identifier>) Purpose: <purpose> Current status (key): <display text> (<key>) Failed trigger (key): <display text> (<key>) The potential reasons for a failed status transition are: ▪ The trigger you are trying to perform is not contained in the graph. ▪ Cannot find a transition for the current status. ▪ Cannot find a fulfillable transition condition for the current status. ▪ There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>. ▪ Cannot evaluate the transition condition (<TR-ID>). ▪ Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.10 GID-2668518 Current load does not match (SR0710.3.6.10)

UI text	Comment
The scale's current load (<scanned barcode>) does not match the expected load (<current load property value>). Cannot use the scale.	Operator can still select a different scale, or the scale's master data needs to be corrected. Message pack: ScaleCurrentLoadChecker<version> Message ID: CurrentLoadDoesNotMatch_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.11 GID-2668519 Unsuccessful scan (SR0710.3.6.11)

UI text	Comment
You have not successfully scanned the load's barcode yet. Please re-confirm to scan a suitable barcode, confirm the load manually by exception, or select another scale.	Message pack: ScaleCurrentLoadChecker<version> Message ID: NothingScanned_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.9 Output Variables (SR0710.9+)

The following output variables are available to reference the phase's output.

4.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

4.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

4.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

4.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

5 Identify Container Phase (SR0750+)

The **Identify container** phase (O Identify Container) allows to identify an equipment entity (container) for the material to be produced and to bind this entity to the context in which it is being used. Appropriate equipment requirements can be defined in support of the fit-for-purpose checks during execution.
The phase can be used during **Output Weighing** and **Dispense**, but it must not be used during **Inline Weighing**.

Example use cases are:

- Verifying that a container meets requirements
  Containers used during processing must meet various requirements. Prior to being used, a container is checked against defined requirements (equipment class and additional properties). The ensuing results are documented in the entity's logbook.
- Exclusive usage of a container for processing an order
  In order to ensure the exclusive usage of a specific container, the entity is bound to a unit procedure. The binding itself is documented in the batch report and the entity's logbook.

The identified container, its equipment class, and the equipment property values are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2668526).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668077)(e.g. requirements are not met).

After completion, the phase displays the identifier of the identified container, both in the Execution Window and in the Navigator.

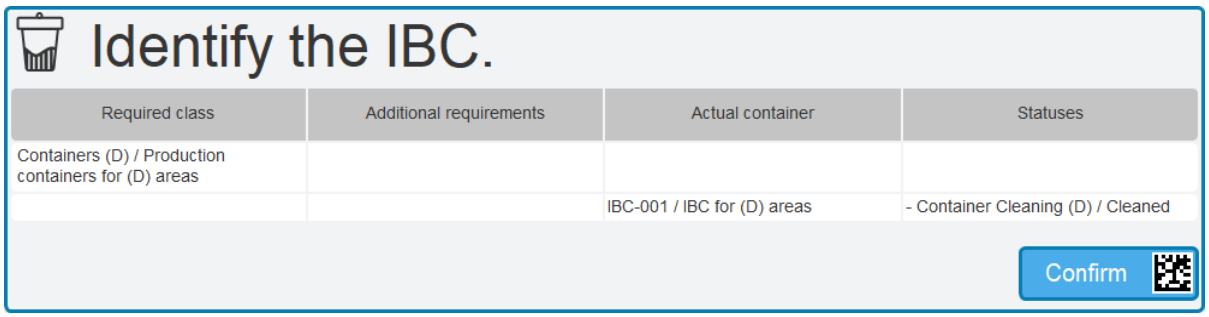

Figure 12: Identify container during execution

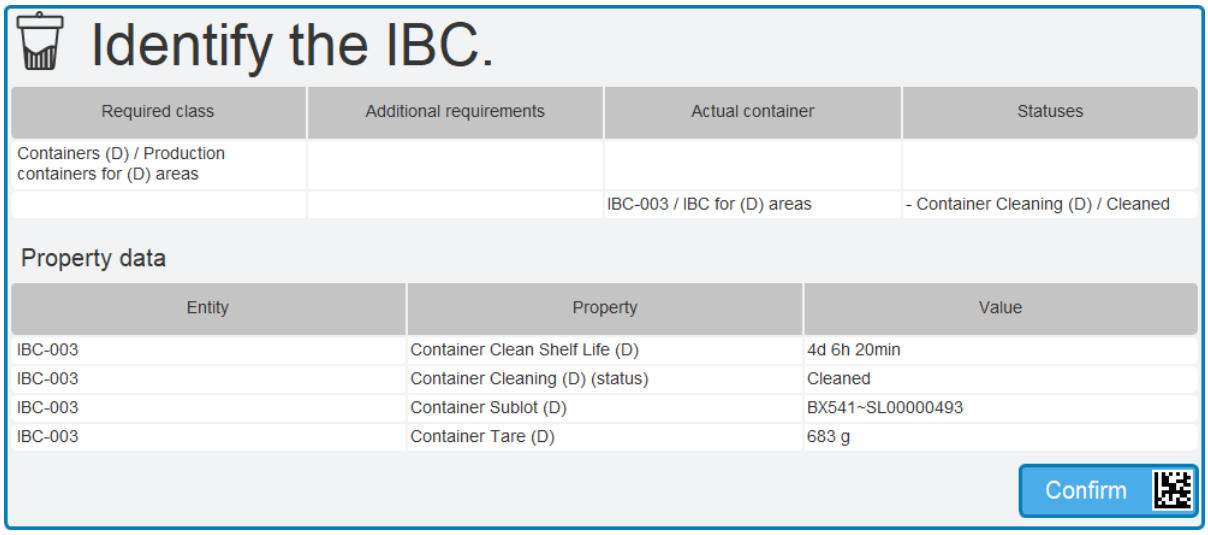

Figure 13: Identify container during execution

5.1 Layout

The phase provides individual layouts for its representation during execution (GID-2668524), in the Navigator (GID-2668525), and in the sub-report (GID-2668526).

5.1.1 Representation during Execution (SR0750.1+)

The representation during execution depends on the phase mode.

5.1.1.1 GID-2669917 Preview mode (SR0750.1.1)

1. Phase-specific icon.
2. <Instruction text>
   (taken from **Instruction (SR0750.8.1)** process parameter (GID-2672019))
3. Table with list of equipment requirements required for identification
   (taken from **Equipment parameters (SR0750.6.1)** process input (GID-2669926))
4. Empty list of property data (Table of property data (SR0750.1.4) (GID-2669920))
5. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.2 GID-2669918 ACTIVE MODE (SR0750.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0750.8.1)** process parameter (GID-2672019))
4. Table with list of equipment requirements required for identification
   (taken from **Equipment parameters (SR0750.6.1)** process input (GID-2669926))
   - Required class
   - Additional requirements [rule identifier / description or rule (if description is empty)]
     (This is related to properties, property values, and status graphs.)
   - Actual container (identified container)
   - Statuses (all actual statuses (available in the used FSM or graph) of the identified container)
5. List of property data (Table of property data (SR0750.1.4) (GID-2669920))
6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.3 GID-2669919 COMPLETED MODE (SR0750.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0750.8.1)** process parameter (GID-2672019))
4. <Container identifier>
5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.4 GID-2669920 TABLE OF PROPERTY DATA (SR0750.1.4)

Only if an **Equipment property list (SR0750.8.11)** bundle process parameter (GID-2672021)is defined.

For all entities of the identified equipment or equipment group that match an **Equipment property list (SR0750.8.11)** bundle process parameter definition, the following data is displayed:

<Entity [identifier]>	<Property [identifier]>	<[Property] Value>

The table is sorted first by entity identifier, secondly by property identifier.

If the **Equipment property list (SR0750.8.11)** bundle process parameter definition contains an equipment class definition, the entity with this attribute is only displayed if the entity is assigned to the defined equipment class.

If the property or equipment graph defined as attribute is not available at the entity, the table entry is omitted and not displayed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2 Representation in Navigator (SR0750.4+)

The Navigator provides the following details:

5.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:
    Identify container

5.1.2.2 GID-2669922 INFORMATION COLUMN (SR0750.4.1)

- <Identifier of identified equipment entity>
  - Example: 23478asUi

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2.3 ACTION COLUMN

- There are no actions available.

5.1.3 Representation in Sub-report (SR0750.5+)

The sub-report contains the following information:

5.1.3.1 Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

5.1.3.2 GID-2669925 Sub-report elements (SR0750.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Position: <number>
- Instruction text
- Required equipment class (identifier and short description)
- Identified container (identifier and short description)
- Additional requirements [rule identifier / description or rule (if description is empty)]
- Actual property names and values (for additional non-status property type-based requirements of the identified container) and all status values (available in the used FSM or graph) of the identified container (e.g. cleaning status)
  - For properties of the **Automation** type, the value is always N/A.
  - List of property data (Table of property data (SR0750.1.4) (GID-2669920))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2 Business Logic (SR0750.2+)

The phase implements the following business logic.

5.2.1 GID-2668527 Phase skipped (SR0750.2.6)

- Function: Phase is skipped
- Trigger: Certain conditions apply during phase activation
- Postcondition: Container identification is skipped and phase is completed automatically

Step	#	Description
Phase performs checks	10	Phase checks ▪ if the **Gross weighing** or **Pallet weighing** method has been selected in the context of Dispense (see **Select scale (SR0210+)** phase in [A3] (GID-2668114)), or ▪ if a **Keep target** situation (target not closed yet) exists in the context of Dispense, or ▪ if, during Output Weighing, an already prepared sublot or container has been identified for weighing, or ▪ if the **Pallet weighing** method has been selected in the context of Output Weighing. If any of these conditions apply, phase skips container identification and is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.2 GID-2668528 Identify and bind equipment entity (SR0750.2.1)

- Function: Identify equipment entity
- Trigger: Phase becomes active
- Postcondition: Equipment entity is identified

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0750.1.2)** layout (GID-2669918).
Operator scans barcode	20	The **Scan equipment entity barcode (SR0750.2.2)** function (GID-2668529)becomes active. For manual identification, see **Enter identifier manually (SR0750.3.1.1)** user-triggered exception (GID-2669941).
Phase performs identification and binding checks	30	The **Identify equipment entity (SR0750.2.3)** function (GID-2668530)becomes active for the container and, in case the container is an equipment group, for all entities of the group. If any check fails the entire equipment group will not be bound.

Step	#	Description
Operator confirms phase	50	▪ If no equipment entity has been bound, phase displays the **Nothing identified (SR0750.3.6.5)** error message (GID-2668544). The phase cannot be completed. ▪ If the checks have passed successfully and an equipment entity has been bound, the operator confirms the identified and bound container. Phase is completed. ▪ If the **Skip container identification (SR0750.3.1.3)** user-triggered exception (GID-2669945)has been signed, phase can be completed without having identified a container.
Phase runs in **Automatic completion** mode	60	In case the container has been identified and bound without any exceptions and the **Mode (SR0750.8.10)** process parameter (GID-2672020)is set to **Automatic completion**, phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.3 GID-2668529 Scan equipment entity barcode (SR0750.2.2)

- Function: Scan an equipment entity barcode
- Trigger: Operator scans barcode
- Postcondition: Equipment entity barcode is scanned

Step	#	Description
Operator scans barcode	10	Phase reads scanned data.
Phase performs checks	20	▪ If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading. ▪ If barcode reading was technically not successful, phase remains in listening mode. ▪ If the required equipment entity is already in the **Identified** or **Bound** status, phase displays the **Already identified (SR0750.3.6.2)** error message (GID-2672020). ▪ If barcode reading was not successful, phase displays the **Cannot find entity (SR0750.3.6.1)** error message (GID-2668539).

Step	#	Description
		If the checks have passed successfully, phase continues with **Identify equipment entity (SR0750.2.3)** function (GID-2668530).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.4 GID-2668530 Identify equipment entity (SR0750.2.3)

- Function: Identify a scanned equipment entity
- Trigger: Equipment entity is scanned successfully
- Postcondition: Equipment entity is identified

Step	#	Description
Phase checks availability of equipment entity	10	If the entity has already been identified or bound in the context of a different phase, the check fails and the phase displays the **Not available for usage (SR0750.3.6.4)** error message (GID-2668543).
	20	If the phase has been resumed and the entity has already been identified in the context of this phase, the phase continues with the **Bind identified equipment entity (SR0750.2.4)** function (GID-2668531).
	30	If the check passes successfully, phase changes the status of the equipment entity to **Identified**, updates the logbook accordingly (if maintained), and continues with the **Bind identified equipment entity (SR0750.2.4)** function (GID-2668531).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.5 GID-2668531 Bind identified equipment entity (SR0750.2.4)

- Function: Bind an identified equipment entity
- Trigger: Equipment entity is identified successfully
- Postcondition: Equipment entity is bound

Step	#	Description
Phase checks expiry status of graphs	10	The **Refresh expired equipment status (SR0750.2.5)** function (GID-2668532)becomes active.
Phase checks equipment type	20	The check requires that the **Container (RS)** property type is assigned to the identified equipment entity. ▪ If the check fails, phase resets the status of the equipment entity to **Available**, updates the binding context and the logbook accordingly (if maintained), and displays the **Wrong equipment type (SR0750.3.6.8)** error message (GID-2668541). ▪ If the check passes successfully, phase continues with the next check.
Phase checks class membership of equipment entity	30	▪ If the check fails, phase resets the status of the equipment entity to **Available**, updates the binding context and the logbook accordingly (if maintained), and displays the **Not member of required class (SR0750.3.6.3)** error message (GID-2668542). ▪ If the check passes successfully, phase continues with the next check.
Phase checks if class and entity fulfill the minimum required status	40	▪ Phase checks for the minimum class status and the minimum entity status required for equipment identification according to the **Container status check (SR0750.8.5)** process parameter (GID-2672025). If the check fails, phase creates the **Container status check (SR0750.3.2.2)** system-triggered exception (GID-2669934). ▪ If the check passes successfully, phase continues with the next check.
Phase checks if property values of equipment entity match and if flexible rules are fulfilled	50	▪ If the check fails, phase creates the **Property value check (SR0750.3.2.1)** system-triggered exception (GID-2669932). If the check passes successfully or the exception is recorded, ▪ phase sets the status of the equipment entity to **Bound** and updates the binding context and the logbook accordingly (if maintained), ▪ phase sends the **CONT_ID** trigger to a status graph of the **Container Cleaning (RS)** purpose in order to trigger a status transition per status graph configuration, and ▪ the container will be available within the given weighing context (Output Weighing or Dispense).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.6 GID-2668532 Refresh expired equipment status (SR0750.2.5)

- Function: Refresh the expired statuses of an equipment entity
- Trigger: Equipment entity is identified successfully
- Postcondition: Expired equipment graph statuses of entity are updated

Step	#	Description
Phase checks if graph statuses are expired	10	Phase checks in a loop for all equipment graphs assigned to the entity if the current status of equipment graph has expired. ▪ If the status is **not expired**, phase checks the next equipment graph. ▪ If the status is **expired**, phase performs the **Expired (RS)** equipment graph trigger and checks the next equipment graph.
	20	If the execution of any **Expired (RS)** equipment graph trigger fails, phase resets the status of the equipment entity to **Available**, updates the binding context and the logbook accordingly (if maintained), and displays the **Expired trigger execution failed (SR0750.3.6.9)** error message (GID-2668540).
	30	If the execution of all **Expired (RS)** equipment graph trigger passed successfully, the phase continues with further checks of the **Bind identified equipment entity (SR0750.2.4)** function (GID-2668531).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3 Recipe Parameters

The phase provides equipment parameters as process inputs (GID-2668533)and process parameters (GID-2668534).

5.3.1 Process Inputs (SR0750.6+)

5.3.1.1 GID-2669926 Equipment parameters (SR0750.6.1)

Equipment parameters allow to define an equipment requirement as follows:

- by assigning an equipment class and
  - by assigning a specific property type (check against existence),
  - by setting specific property values (check against value, see **Technical Property Types and Editors (SR3071.8.7+)** in "Functional Requirement Specification Data Management" [A4] (GID-2668114)),

- by defining a flexible rule, or
- by defining a conditional rule.

For properties of the following data types, the property values cannot be accessed within rules:

- Equipment type
- Flexible tag definition
- Ranges
- Room cleaning rules
- Scale configuration
- Work center assignment

For details about rules, see **Expressions for Flexible Rules (SR3146.9.9.4.10)** and **Expressions for Conditional Rules (SR3146.9.9.4.12)** in "Functional Requirement Specification Recipe and Workflow Management" [A5] (GID-2668114).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2 Process Parameters (SR0750.8+)

The following process parameters define the behavior of the phase.

5.3.2.1 Instruction Table-specific Parameters

5.3.2.1.1 Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

5.3.2.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

5.3.2.2 INSTRUCTION LINK-SPECIFIC PARAMETERS

5.3.2.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2672018). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

5.3.2.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.

Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

5.3.2.3 BASIC PARAMETERS

5.3.2.3.1 GID-2672019 INSTRUCTION (SR0750.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.3.2 GID-2672020 MODE (SR0750.8.10)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion (default)**: Operator confirms phase manually. **Automatic completion**: Phase is completed automatically after a container has been identified successfully.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.3.3 GID-2672021 EQUIPMENT PROPERTY LIST (SR0750.8.11)

The phase allows up to ten bundle process parameters of this type.

Attribute	Type	Comment
Equipment class	Equipment class object	Optional. Prefilled with the last value used. If defined, an attribute of the equipment entity is only then displayed during execution if the entity is assigned to this equipment class.
Attribute	String	Property type or equipment graph whose data shall be displayed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.3.4 EQUIPMENT CLASS SELECTION EDITOR ()

The system provides an Equipment Class Selection editor for selecting an equipment class from the Universe. Equipment classes in a **Retired** state (e.g. Archived) are not available for selection.

5.3.2.3.5 ATTRIBUTE SELECTION EDITOR ()

The system provides an Attribute Selection editor for selecting a property type or an equipment graph property (status or expiry date).
If an equipment class has been defined with the Equipment Class Selection editor of the process parameter, only properties of the selected equipment class are displayed.

5.3.2.4 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

5.3.2.4.1 GID-2672024 PROPERTY VALUE CHECK (SR0750.8.2)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Property value check (SR0750.3.2.1)** system-triggered exception (GID-2669932).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.4.2 GID-2672025 CONTAINER STATUS CHECK (SR0750.8.5)

Attribute	Type	Comment
Minimum class status	Choice list	Defines the minimum status of classes defined with the **Equipment parameters (SR0750.6.1)** process input (GID-2669926)that is required for container (group) identification. Available settings: **Verification**, **Approved**. Default setting: **Approved**.
Minimum entity status	Choice list	Defines the minimum entity status required for container (group) equipment identification. Available settings: **Verification**, **Approved**. Default setting: **Approved**.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Container status check (SR0750.3.2.2)** system-triggered exception (GID-2669934).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.4.3 GID-2672026 UNFORESEEN RESUME (SR0750.8.6)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Unforeseen resume (SR0750.3.2.4)** system-triggered exception (GID-2669937).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.4.4 GID-2672027 STATUS TRANSITION FAILED (SR0750.8.9)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Status transition failed (SR0750.3.2.5)** system-triggered exception (GID-2669939).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.5 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

5.3.2.5.1 GID-2672028 ENTER IDENTIFIER MANUALLY (SR0750.8.3)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Enter identifier manually (SR0750.3.1.1)** user-triggered exception (GID-2669941).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.5.2 GID-2672029 UNBIND (SR0750.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Unbind (SR0750.3.1.2)** user-triggered exception (GID-2669943).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.5.3 GID-2672030 SKIP CONTAINER IDENTIFICATION (SR0750.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Skip container identification (SR0750.3.1.3)** user-triggered exception (GID-2669945).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.2.5.4 GID-2672031 RETURN TO MATERIAL MANAGEMENT (SR0750.8.7)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Return to material management (SR0750.3.1.4)** user-triggered exception (GID-2669947).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4 Exceptions (SR0750.3+)

The phase supports user-defined, user-triggered (GID-2668536), system-triggered (GID-2668535), and post-completion exceptions (GID-2668537)and their configuration by means of process parameters (GID-2668534).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

5.4.1 System-triggered Exceptions (SR0750.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

5.4.1.1 GID-2669932 Property value check (SR0750.3.2.1)

For each property that does not match, the exception lists the related rule identifier, the rule description (or the rule content, if the description is not maintained), the property identifier, and the expected and actual values.
For each flexible rule that is not fulfilled, the exception lists the related rule identifier, the rule description (or the rule expression, if the description is not maintained), and the expected and actual values of the expression.

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Property value check (SR0750.8.2)** process parameter (GID-2672024))
  Cannot identify the <Identifier of identified equipment entity> entity, since it does not meet the defined equipment requirements.

Exception Window

- <Exception text>
  (taken from **Property value check (SR0750.8.2)** process parameter (GID-2672024))
  Cannot identify the <Identifier of identified equipment entity> entity, since it does not meet the defined equipment requirements.

  Rule: <identifier>
  Description: <rule description> (or <rule content/expression>, if the description is not maintained)
- For properties that do not match:
  Equipment property: <identifier>
  Expected value: <value>
  Actual value: <value>

- For rules that are not fulfilled:
  Expected value: Yes
  Actual value: No
- Example:
  Equipment requirement violation
  Cannot identify the AX67 entity, since it does not meet the defined equipment requirements.

  Rule: Rule_01
  Description: Check of cleaning status
  Equipment property: Cleaning status
  Expected value: Clean
  Actual value: To be cleaned

  Rule: Rule_02
  Description: Required volume range
  Equipment property: Volume
  Expected value: 150 - 200 l
  Actual value: 100 l

  Rule: Rule_03
  Description: Counter less or equal 5
  Expected value: Yes
  Actual value: No

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.2 GID-2669933 PROPERTY VALUE CHECK - LOGIC (SR0750.3.2.1.1)

- Trigger: Check has failed
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	1-10	Phase shows exception description to be signed.

Step	#	Description
Operator signs exception	1-20	▪ Phase records the exception. ▪ Phase sets status of equipment entity to **Bound** and updates the binding context and the logbook accordingly (if maintained). ▪ Phase sends the **CONT_ID** trigger to a status graph of the **Container Cleaning (RS)** purpose in order to trigger a status transition per status graph configuration. ▪ The container will be available within the given weighing context (Output Weighing or Dispense).
Operator does not accept exceptional situation	2-10	Phase resets status of equipment entity to **Available** and updates the binding context and the logbook accordingly (if maintained).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.3 GID-2669934 CONTAINER STATUS CHECK (SR0750.3.2.2)

The phase checks if the defined minimum statuses for the equipment class and entity are fulfilled according to the **Container status check (SR0750.8.5)** process parameter (GID-2672025).

The check either applies to a container as a single entity and its required class, or, in case of an entity group, to its required class and the main parent entity and to all child entities, respectively.

In addition, the check applies to all classes (including the classes of child entities) that are explicitly defined as an equipment requirement with a conditional rule and the **equipmentIsMemberOfClass** function. For details, see **Expressions for Conditional Rules (SR3146.9.9.4.12)** and **Expression Editor - Runtime Context Data (SR3146.9.9.6)** in "Functional Requirement Specification Recipe and Workflow Management" [A5] (GID-2668114).

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Container status check (SR0750.8.5)** process parameter (GID-2672025))
  (Class status does not match:)
  Cannot identify the <entity identifier > equipment entity, since its required class (<class identifier>) is in the <status> status.

  (Entity status does not match:)
  Cannot identify the <identifier> equipment entity, since it is in the <status> status.

Exception Window

- <Exception text>
  (taken from **Container status check (SR0750.8.5)** process parameter (GID-2672025))
  (Class status does not match:)
  Cannot identify the <entity identifier > equipment entity, since its required class (<class identifier>) is in the <status> status.
  Required minimum status: <status>

  (Entity status does not match:)
  Cannot identify the <identifier> equipment entity, since it is in the <status> status.
  Required minimum status: <status>

  - Example:
    Equipment status violation
    Cannot identify the AX67 equipment entity, since its required class (CX14) is in the Verification status.
    Required minimum status: Approved

    Cannot identify the AX67 equipment entity, since it is in the Draft status.
    Required minimum status: Approved

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.4 GID-2669935 CONTAINER STATUS CHECK - LOGIC (SR0750.3.2.2.1)

- Trigger: Check has failed
- Postcondition: Exception is recorded

Step	#	Description
Operator accepts exceptional situation	1-10	Phase shows exception description to be signed.
Operator signs exception	1-20	▪ Phase records the exception. ▪ Phase sets status of equipment entity to **Bound** and updates the binding context and the logbook accordingly (if maintained). ▪ Phase sends the **CONT_ID** trigger to a status graph of the **Container Cleaning (RS)** purpose in order to trigger a status transition per status graph configuration. ▪ The container will be available within the given weighing context (Output Weighing or Dispense).

Step	#	Description
		▪ In case the container is an equipment group, the binding is performed and the trigger is sent for each equipment entity of the equipment group.
Operator does not accept exceptional situation	2-10	Phase resets status of equipment entity to **Available** and updates the binding context and the logbook accordingly (if maintained). In case the container is an equipment group, this is done for each equipment entity of the equipment group.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.5 GID-2669936 MULTIPLE FAILED CHECKS (SR0750.3.2.3)

In case multiple system-triggered exceptions occur, only one combined exception (system-triggered exception) is recorded including information about all exceptions. The highest risk assessment of all related exceptions and its related signature privilege apply.

After the exception has been recorded, the phase must be manually completed.

Representation in the message dialog:

6. Several exceptions have occurred.
   For details navigate to the Exception Window.
7. Exception button

Representation during exception handling:

8. Exception text:
   <Concatenation of multiple exception texts>.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.6 GID-2669937 UNFORESEEN RESUME (SR0750.3.2.4)

Representation of the exception:

- <Exception text>
  (taken from **Unforeseen resume (SR0750.8.6)** process parameter (GID-2672026))
  The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.

- Example:
  A critical resume situation has occurred. Contact your supervisor before proceeding.
  The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.7 GID-2669938 UNFORESEEN RESUME - LOGIC (SR0750.3.2.4.1)

- Trigger: Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

Step	#	Description
Phase activation	10	Phase displays the **Unforeseen resume (SR0750.3.2.4)** system-triggered exception.
Operator triggers exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.8 GID-2669939 STATUS TRANSITION FAILED (SR0750.3.2.5)

The **Status transition failed** exception is displayed automatically if a certain status transition could not be performed based on the given graph purpose and trigger.

In case the trigger was executed on a container and the container is an equipment group, multiple failed transitions on different entities can be reported combined in one exception.

The potential reasons for a failed status transition are:

- The graph of the required purpose is missing.
- The trigger is missing.
- Source status does not match.
- Condition cannot be fulfilled or is not unique (in case of multiple transition definitions per trigger).
- Error during condition evaluation.
- Error during action evaluation.

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Status transition failed (SR0750.8.9)** process parameter (GID-2672027))
  <the reason that applies>
  - List of potential reasons:
  - The graph of the required purpose is missing.
  - The trigger you are trying to perform is not contained in the graph.
  - Cannot find a transition for the current status.
  - Cannot find a fulfillable transition condition for the current status.
  - There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.
  - Cannot evaluate the transition condition (<TR-ID>).
  - Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

Exception Window

- <Exception text>
  (taken from **Status transition failed (SR0750.8.9)** process parameter (GID-2672027))
  <reason>
  Equipment: <equipment identifier> / <equipment short description>
  Equipment type: <list of equipment types> (if available)
  Graph (ID): <graph display text> (<identifier>)
  Purpose: <purpose>
  Current status (key): <display text> (<key>)
  Failed trigger (key): <display text> (<key>)
  - Example:
    Status transition failed.
    Cannot find a transition for the current status.
    Equipment: IBC0033
    Equipment type: Container (RS)
    Graph (ID): IBC Cleaning (IBCCleaning01)
    Purpose: Container Cleaning (RS)
    Current status (key): Blocked (BLOCKED)
    Failed trigger (key): In use (IN_USE)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.1.9 GID-2669940 STATUS TRANSITION FAILED - LOGIC (SR0750.3.2.5.1)

- Trigger: The status transition could not be performed based on the given graph purpose and trigger.
- Postcondition: Phase is active

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2 User-triggered Exceptions (SR0750.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

5.4.2.1 GID-2669941 ENTER IDENTIFIER MANUALLY (SR0750.3.1.1)

The **Enter identifier manually** exception allows an operator to enter the barcode of an equipment entity manually.

The exception is disabled, if the required equipment entity is already in the **Identified** or **Bound** status.

Representation during exception handling:

- Instruction:
  Identify by typing the container barcode.
  Box for identifier input.
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Enter identifier manually (SR0750.8.3)** process parameter (GID-2672028))
  Manual entry: <barcode string>
  - Example:
    Equipment entity barcode entered manually
    Manual entry: 23478asUi

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.2 GID-2669942 Enter identifier manually - Logic (SR0750.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: Barcode string is entered manually

Step	#	Description
Operator confirms exception	10	If entered barcode string does not match an equipment entity, phase displays the **Cannot find entity (SR0750.3.6.1)** error message (GID-2668539).
Operator signs exception	20	If equipment entity can be identified as an existing entity and exception is signed, phase continues with **Identify equipment entity (SR0750.2.3)** function (GID-2668530)(see also **Identify and bind equipment entity (SR0750.2.1)** function (GID-2668528)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.3 GID-2669943 Unbind (SR0750.3.1.2)

The **Unbind** exception allows an operator to revoke the identification of a container.

The exception is disabled, if the required container is not in the **Bound** status.

Representation during exception handling:

- Instruction:
  Confirm to unbind the container.
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Unbind (SR0750.8.4)** process parameter (GID-2672029)
  Unbound container: <Equipment entity identifier> / <Equipment entity short description>
  - Example:
    Unbind during identification process
    Unbound container: 23478H / Hose 45 cm

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.4 GID-2669944 UNBIND - LOGIC (SR0750.3.1.2.1)

- Trigger: Exception is selected
- Postcondition: Equipment entity is no longer bound

Step	#	Description
Operator confirms exception	10	Phase shows exception description to be signed according to **Unbind (SR0750.8.4)** process parameter (GID-2672029).
Operator signs exception	20	Phase resets status of equipment entity to **Available** and updates the binding context and the logbook accordingly (Unbind) (if maintained).
		Phase sends the **CONT_EMPTY** trigger to a status graph of the **Container Cleaning (RS)** purpose in order to trigger a status transition per status graph configuration.
		The container will no longer be available within the given weighing context (Output Weighing or Dispense).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.5 GID-2669945 SKIP CONTAINER IDENTIFICATION (SR0750.3.1.3)

The **Skip container identification** exception allows an operator to skip the identification of a container.

The exception is disabled if the required container is already in the **Identified** or **Bound** status.

Representation during exception handling:

- Instruction:
  Skip container identification.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Skip container identification (SR0750.8.8)** process parameter (GID-2672030))
  No container identified.
  - Example:
    Container identification has been skipped.
    No container identified.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.6 GID-2669946 SKIP CONTAINER IDENTIFICATION - LOGIC (SR0750.3.1.3.1)

- Trigger: Exception is selected
- Postcondition: Phase can be completed without container identification

Step	#	Description
Operator confirms exception	10	Phase shows exception description to be signed according to **Skip container identification (SR0750.8.8)** process parameter (GID-2672030).
Operator signs exception	20	Phase returns to the Execution Window and can be completed without having identified a container.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.7 GID-2669947 RETURN TO MATERIAL MANAGEMENT (SR0750.3.1.4)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.
In the context of Dispense operations, the exception allows the operator to start a new run with processing the **D Identify material** phase.

Representation during exception handling:

- Instruction:
  Return to material management.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Return to material management (SR0750.8.7)** process parameter (GID-2672031))
  - Example:
    Back to material management.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.2.8 GID-2669948 RETURN TO MATERIAL MANAGEMENT - LOGIC (SR0750.3.1.4.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator confirms exception	10	Phase records the exception.
	20	Phase is completed automatically and returns to the **Manage produced material (SR0700+)** phase (GID-2668053)(Output Weighing context) or the **Identify material (SR0200+)** phase (Dispense context, [A3] (GID-2668114)).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

5.5 Information Messages

There are no information messages available.

5.6 Questions

There are no questions available.

5.7 Decisions

There are no decisions available.

5.8 Error Messages (SR0750.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

5.8.1 GID-2668538 Already identified (SR0750.3.6.2)

UI text	Comment
Cannot identify the <scanned identifier> container, since you have already identified a suitable container. To identify another container, unbind the <currently identified identifier> container first.	Message pack: ow_IdentCont<version> Message ID: EqReqAlreadyIdent_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.2 GID-2668539 Cannot find entity (SR0750.3.6.1)

UI text	Comment
Cannot identify the <scanned identifier> container, since it is not available in the system.	Message pack: ow_IdentCont<version> Message ID: EqNotExist_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.3 GID-2668540 Expired trigger execution failed (SR0750.3.6.9)

UI text	Comment
The <equipment identifier> entity is not suitable, since the update of at least one expired status failed.	Message pack: pec_ExceptionMessage Message ID: cannotIdentifyExpiryTriggerFailure_ErrorMsg The **Details** button provides access to more graph-specific information: <the reason that applies> Equipment: <equipment identifier> / <equipment short description> Equipment type: <list of equipment types> (if available) Graph (ID): <graph display text> (<identifier>) Purpose: <purpose> Current status (key): <display text> (<key>) Failed trigger (key): <display text> (<key>) The potential reasons for a failed status transition are: ▪ The trigger you are trying to perform is not contained in the graph. ▪ Cannot find a transition for the current status. ▪ Cannot find a fulfillable transition condition for the current status. ▪ There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>. ▪ Cannot evaluate the transition condition (<TR-ID>). ▪ Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.4 GID-2668541 Wrong equipment type (SR0750.3.6.8)

UI text	Comment
<Scanned identifier> is not a suitable equipment entity. Please identify a container.	Message pack: ow_IdentCont<version> Message ID: WrongEquipmentType_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.5 GID-2668542 Not member of required class (SR0750.3.6.3)

UI text	Comment
The <scanned identifier> equipment entity is not suitable, since it does not belong to the required class (<class identifier>).	Message pack: eqm.Validation Message ID: eqmClassNotMatch_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.6 GID-2668543 Not available for usage (SR0750.3.6.4)

UI text	Comment
Cannot identify the <identifier> equipment entity, since it has already been identified or bound at the <identifier> work center for <workflow, order> (unit procedure: <identifier>, operation: <identifier>, phase: <identifier>).	Message pack: fsm_S88EquipmentBinding Message ID: identifyNotAllowedOwnedByOther_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.7 GID-2668544 Nothing identified (SR0750.3.6.5)

UI text	Comment
You have to identify a container before you can confirm the phase.	Message pack: ow_IdentCont<version> Message ID: EqNotIdentified_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

5.9 Output Variables (SR0750.9+)

The following output variables are available to reference the phase's output.

5.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

5.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

5.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

5.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

5.9.5 GID-2668549 Container object (SR0750.9.1)

- Data type: IMESS88Equipment
- Usage: The output variable provides the complete object of the identified equipment entity. This is the output to use in subsequent phases for accessing data of the equipment object, such as changing its status or writing a property.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.6 GID-2668550 Container ID (SR0750.9.2)

- Data type: String
- Usage: The output variable provides the identifier of the identified equipment entity for displaying it as text.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.7 GID-2668551 Container short description (SR0750.9.3)

- Data type: String
- Usage: The output variable provides the short description of the identified equipment entity for displaying it as text.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6 Tare Phase (SR0720+)

The **Tare** phase (O Tare) allows an operator to record the actual tare of a target container.

It precedes the **Weigh** phase and displays in real-time the tare weight of the container placed on the scale connected to the work center. Depending on the weighing method, scale availability, or scale configuration, taring happens automatically, manually with automatic scale communication, or offline by operator input only. The operator confirms the tare value by scanning the barcode of the scale.
Additionally, the phase is skipped, if the tare of the identified container or sublot is already known.
If the **Quantity entry** weighing method is selected, the phase is skipped.
Details of the tare value are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report.
Anomalies that occur during processing are covered by the phase exception handling (e.g. redo zero, using an offline tare).
After completion the phase displays the registered tare weight, both in the Execution Window and in the Navigator.

Figure 14: Tare during execution

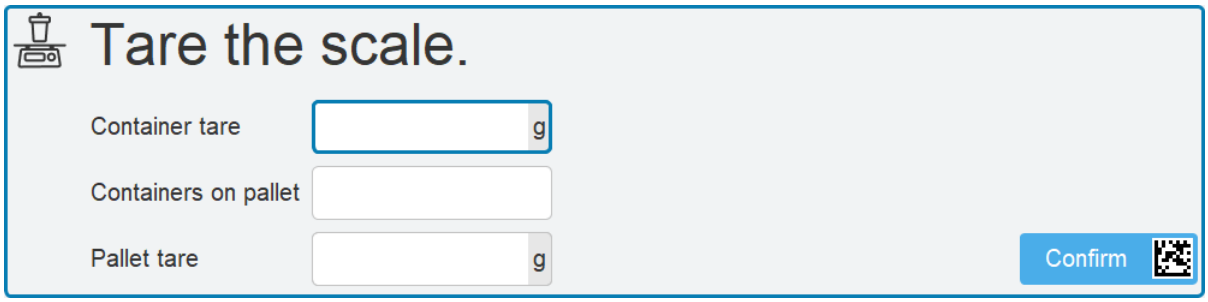

Figure 15: Tare during execution

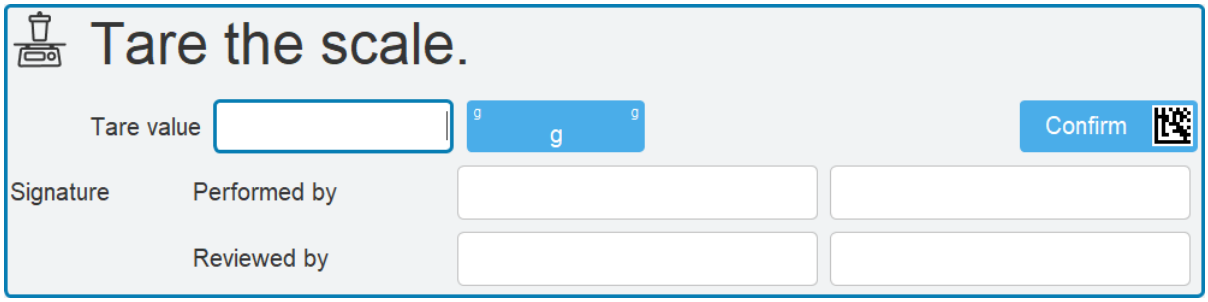

Figure 16: Tare during execution

6.1 Layout

The phase provides individual layouts for its representation during execution (GID-2668552), in the Navigator (GID-2668553). and in the sub-report (GID-2668554)

6.1.1 Representation during Execution (SR0720.1+)

The representation during execution depends on the phase mode.

6.1.1.1 GID-2669949 Preview mode (SR0720.1.1)

1. Phase-specific icon.
2. <Instruction text>
   (taken from **Instruction (SR0720.8.1)** process parameter (GID-2672036))
3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.2 GID-2669950 Active mode (automatic tare) (SR0720.1.2)

Does not apply if scale is configured as manual scale.

This representation applies to **Net** weighing method. The tare type is **Automatic**.
If a phase completion signature is assigned to the phase, the signature is ignored during execution.

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0720.8.1)** process parameter (GID-2672036))
4. <Tare value>
5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.3 GID-2669951 ACTIVE MODE (MANUAL TARE) (SR0720.1.3)

Does not apply if scale is configured as manual scale.

This representation applies to **Gross** and **Pallet** weighing methods. The tare type is **Manual**, i.e. the tare value has been entered manually before it is automatically sent to the scale.
The recipe author must assign a phase completion signature to the phase in order to require the operator to sign the manual entry of tare values.
If a **Use offline tare (SR0720.3.1.3)** user-triggered exception (GID-2669983)has been recorded, the input boxes are read-only.

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0720.8.1)** process parameter (GID-2672036))
4. Container tare, input box.
5. Additionally for **Pallet** weighing:
6. Number of containers on pallet, input box.
7. Pallet tare, input box.
8. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.4 GID-2669952 ACTIVE MODE (MANUAL SCALE) (SR0720.1.6)

This representation applies to all weighing methods if the selected scale is configured as manual scale. The tare type is **Offline**, i.e. the tare value is entered manually, but not sent to the scale.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0720.8.1)** process parameter (GID-2672036))
4. Input box and **UoM** toggle button.
   - For **Net** weighing method.
   - The **UoM** toggle button provides all UoMs that are supported by the manual scale.

5. Container tare, input box and **UoM** toggle button.
   - For **Gross** and **Pallet** weighing methods.
   - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
6. Additionally for **Pallet** weighing:
   1. Number of containers on pallet, input box.
   2. Pallet tare, input box and **UoM** toggle button.
   - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
7. Phase completion signature panel
   - **WD_ES_MANUAL_SCALE** access privilege.
8. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.5 GID-2669953 COMPLETED MODE (SR0720.1.4)

This representation applies to **Net** and **Gross** weighing methods.

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. Tare
4. <Tare value>
5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.6 GID-2669954 COMPLETED MODE (PALLET WEIGHING) (SR0720.1.5)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. Tare
4. <Number of containers> x <container tare>

5. <Pallet tare>
6. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2 Representation in Navigator (SR0720.4+)

The Navigator provides the following details:

6.1.2.1 Phase column (Framework capability)

- <Phase name>
  - Example:
    Tare Scale

6.1.2.2 GID-2669956 Information column (SR0720.4.1)

- <Total tare value>
  - Example:
    10.0 g

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2.3 Action column

- There are no actions available.

6.1.3 Representation in Sub-report (SR0720.5+)

The sub-report contains the following information:

6.1.3.1 Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

6.1.3.2 GID-2669959 Sub-report elements (SR0720.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Position: <number>
- For **Net** weighing and **Gross** weighing:
  Tare: <Tare value>
  Tare type: <tare type>
- For **Pallet** weighing:
  Container tare: <number of containers> x <container tare>
  <Pallet tare>: <pallet tare>
  Tare type: <tare type>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2 Business Logic (SR0720.2+)

The phase implements the following business logic.

6.2.1 Main Path

Business logic related to the main path:

6.2.1.1 GID-2669960 Continuous read of scale (SR0720.2.1)

Does not apply if scale is configured as manual scale.

- Function: Continuous reading of scale value
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: N/A

Step	#	Description
Phase activation	10	Phase establishes communication to the scale. If no communication can be established to the scale, phase displays the **Scale online error (SR0720.3.6.1)** error message (GID-2668564).
	20	Phase continuously displays the scale value.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.1.2 GID-2669961 TARE (MANUAL SCALE) (SR0720.2.9)

Applies only if scale is configured as manual scale.

- Function: Taring with a scale that is configured as manual scale
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: N/A

Step	#	Description
Phase activation	10	Phase displays the **Active mode (manual scale) (SR0720.1.6)** layout (GID-2669952).
	20	Operator enters current tare value manually, even in case of **Net** weighing.
Phase completion signature	30	Pre-defined phase completion signature is requested according to the **WD_ES_MANUAL_SCALE** access privilege. Any other phase completion signature that has been assigned to the phase is ignored.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.1.3 GID-2669962 CONFIRM BY SCAN (SR0720.2.2)

- Function: Confirm phase by use of barcode scan
- Type: Main path
- Trigger: Operator scans scale
- Postcondition: Phase is completed

Step	#	Description
Operator scans scale	10	If another scale than the selected scale was scanned, phase displays the **Wrong scale (SR0720.3.6.2)** error message (GID-2668565).

Step	#	Description
	20	If no stable tare value can be read, phase displays the **Scale driver error (SR0720.3.6.4)** error message (GID-2668567). For **Gross** weighing, see **Weighing method - Gross (SR0720.2.4)** function (GID-2669965)and **Weighing method - Gross (manual scale) (SR0720.2.11)** function (GID-2669966). For **Pallet** weighing, see **Weighing method - Pallet (SR0720.2.5)** function (GID-2669967)and **Weighing method - Pallet (manual scale) (SR0720.2.12)** function (GID-2669968).
	25	If the current load (tare value) is outside of the scale's allowed weighing range, phase displays the **Tare above valid range (SR0720.3.6.5)** error message (GID-2668568). The scale's allowed load is calculated as follows: Minimum allowed load = scale's lower range value + scale resolution Maximum allowed load = scale's upper range value – scale resolution
	30	Phase is completed automatically. In case the scale is configured as manual scale, the tare type is set to **Offline**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.1.4 GID-2669963 CONFIRM BY BUTTON (SR0720.2.3)

- Function: Confirm phase by use of button
- Type: Main path
- Trigger: Operator confirms phase
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	If no stable tare value can be read, phase displays the **Scale driver error (SR0720.3.6.4)** error message (GID-2668567). For **Gross** weighing, see **Weighing method - Gross (SR0720.2.4)** function (GID-2669965)and **Weighing method - Gross (manual scale) (SR0720.2.11)** function (GID-2669966). For **Pallet** weighing, see **Weighing method - Pallet (SR0720.2.5)** function (GID-2669967)and **Weighing method - Pallet (manual scale) (SR0720.2.12)** function (GID-2669968).

Step	#	Description
	15	If the current load (tare value) is outside of the scale's allowed weighing range, phase displays the **Tare above valid range (SR0720.3.6.5)** error message (GID-2668568). The scale's allowed load is calculated as follows: Minimum allowed load = scale's lower range value + scale resolution Maximum allowed load = scale's upper range value – scale resolution
	20	Phase is completed automatically. In case the scale is configured as manual scale, the tare type is set to **Offline**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.1.5 GID-2669964 GET TARE VALUE FROM PREPARED SUBLOT (SR0720.2.8)

- Function: Phase gets tare value automatically
- Type: Main path
- Trigger: Already prepared sublot has been identified within the **Manage produced material (SR0700+)** phase (GID-2668053)
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase receives the tare value automatically, since it is already known for prepared sublots.
	20	Only if the selected scale is not configured as manual scale: The tare value is sent to the scale, so that the scale reading reflects the actual net value. Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.2 Weighing Method-specific Paths

Business logic related to weighing methods:

6.2.2.1 GID-2669965 Weighing method - Gross (SR0720.2.4)

Does not apply if scale is configured as manual scale.

- Function: Use of **Gross**/**Gross removal**
- Type: Special handling of weighing methods other than **Net** weighing
- Trigger: Specific weighing method is selected
- Postcondition: N/A

Step	Description
Phase activation	Phase displays **Active mode (manual tare) (SR0720.1.3)** layout (GID-2669951).
Use offline tare (SR0720.3.1.3) user-triggered exception (GID-2669983)	If available, the tare value entered in the **Active mode (manual tare) (SR0720.1.3)** layout link is populated.
Operator scans scale or confirms phase (**Confirm by scan (SR0720.2.2)** function link, **Confirm by button (SR0720.2.3)** function link)	The manually entered tare value is sent to the scale, so that the scale reading reflects the actual net value.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.2.2 GID-2669966 Weighing method - Gross (manual scale) (SR0720.2.11)

- Function: Use of **Gross**/**Gross removal**, scale is configured as manual scale
- Type: Special handling of weighing methods other than **Net** weighing
- Trigger: Specific weighing method is selected
- Postcondition: N/A

Step	Description
Phase activation	Phase displays **Active mode (manual scale) (SR0720.1.6)** layout (GID-2669952).
Operator scans scale or confirms phase (**Confirm by scan (SR0720.2.2)** function (GID-2669962), **Confirm by button (SR0720.2.3)** function (GID-2669963))	Tare is recorded with the **Offline** tare type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.2.3 GID-2669967 WEIGHING METHOD - PALLET (SR0720.2.5)

Does not apply if scale is configured as manual scale.

- Function: Use of **Pallet**
- Type: Special handling of weighing methods other than **Net** weighing
- Trigger: Specific weighing method is selected
- Postcondition: N/A

Step	Description
Phase activation	Phase updates representation according to the **Active mode (manual tare) (SR0720.1.3)** layout (GID-2669951)for **Pallet** weighing.
Operator scans scale or confirms phase (**Confirm by scan (SR0720.2.2)** function (GID-2669962)**Confirm by button (SR0720.2.3)** function (GID-2669963))	Phase checks the actual net weight loaded on the scale against the allowed upper tolerance.
	Tare is recorded and sent to the scale, so that the scale reading reflects the actual net value.

Step	Description
Use offline tare (SR0720.3.1.3) user-triggered exception (GID-2669983)	If available, the values entered in the **Active mode (manual tare) (SR0720.1.3)** layout (GID-2669951)are populated.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.2.4 GID-2669968 WEIGHING METHOD - PALLET (MANUAL SCALE) (SR0720.2.12)

- Function: Use of **Pallet**, scale is configuration as manual scale
- Type: Special handling of weighing methods other than **Net** weighing
- Trigger: Specific weighing method is selected
- Postcondition: N/A

Step	Description
Phase activation	Phase updates representation according to the **Active mode (manual scale) (SR0720.1.6)** layout (GID-2669952)for **Pallet** weighing.
Operator scans scale or confirms phase (**Confirm by scan (SR0720.2.2)** function (GID-2669962), **Confirm by button (SR0720.2.3)** function (GID-2669963))	Phase checks the actual net weight loaded on the scale against the allowed upper tolerance.
	Tare is recorded with the **Offline** tare type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.3 Equipment Management

Business logic related to equipment management:

6.2.3.1 GID-2669969 CONTAINER MANAGEMENT (SR0720.2.10)

- Function: Manage container
- Type: Special handling of container tare
- Precondition: Container must be of the **Container (RS)** equipment type
- Trigger: Empty or prepared target container has been identified during Output Weighing
- Postcondition: Data was retrieved from a container's property of the **Current Tare (RS)** purpose

Step	Description
Case: Already prepared container has been identified with the **Manage produced material (SR0700+)** phase (GID-2668053)	In deviation from the **Get tare value from prepared sublot (SR0720.2.8)** function (GID-2669964), phase receives the tare value automatically from a prepared container's property of the **Current Tare (RS)** purpose. Only if the selected scale is not configured as manual scale: The tare value is sent to the scale, so that the scale reading reflects the actual net value. Phase is completed automatically.
Case: Phase activation with known target container in combination with **Gross** weighing	In deviation from the **Weighing method - Gross (SR0720.2.4)** function (GID-2669965), phase receives the tare value automatically from a prepared container's property of the **Current Tare (RS)** purpose. Only if the selected scale is not configured as manual scale: The tare value is sent to the scale, so that the scale reading reflects the actual net value. Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.3.2 GID-2669970 CHECK CONTAINER TARE (SR0720.2.13)

NOTE: Does not apply to O Tare (RS) [5.0], [5.1].

- Function: Check container tare value against a reference value
- Type: Specific business logic related to container management
- Precondition: Tare check is enabled according to the **Tare check configuration (SR0720.8.6)** process parameter (GID-2672038)
- Trigger: Operator confirms phase
- Postcondition: Specific business logic applies

Step	Description
Phase completion **Case**: In **Net** weighing, a target container has been selected and **Tare check** is enabled. or **Case**: In **Gross** weighing, a target container to be weighed has been selected and **Tare check** is enabled.	The tare tolerances are calculated based on the tolerance values derived from **Tare check tolerance definition (SR0720.8.7)** process parameter (GID-2672037)in the recipe, the container's property of the **Reference Tare (RS)** purpose, and the resolution of the selected scale: Lower tolerance = round up according to scale resolution (reference tare - lower tolerance value (recipe) + scale resolution, Upper tolerance = round down according to scale resolution (reference tare + upper tolerance value (recipe) – scale resolution If the tolerance value (recipe) is provided as a percentage value, it is converted into an absolute value using the property of the **Reference Tare (RS)** purpose. If the lower and/or upper tolerances (recipe) are not maintained, it is assumed to be 0 for the tolerance calculation. In case the container's actual tare is not within the calculated tolerances, phase creates the **Failed tare check (SR0720.3.2.2)** system-triggered exception (GID-2669976).
Phase completion **Case**: No target container has been selected and **Tare check** is enabled.	Phase creates the **Failed tare check (SR0720.3.2.2)** system-triggered exception (GID-2669976)since no target container is available for which the tare check can be performed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3 Recipe Parameters

The phase provides process parameters (GID-2668558).

6.3.1 Process Parameters (SR0720.8+)

The following process parameters define the behavior of the phase.

6.3.1.1 Instruction Table-specific Parameters

6.3.1.1.1 Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

6.3.1.1.2 Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

6.3.1.2 Instruction Link-specific Parameters

6.3.1.2.1 Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2672035). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

6.3.1.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

6.3.1.3 BASIC PARAMETERS

6.3.1.3.1 GID-2672036 INSTRUCTION (SR0720.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.1.3.2 GID-2672037 TARE CHECK TOLERANCE DEFINITION (SR0720.8.7)

Attribute	Type	Comment
Lower tolerance	MeasuredValue	Defines the lower tolerance as a percentage or absolute value including unit of measure for the tare check.
Upper tolerance	MeasuredValue	Defines the upper tolerance as a percentage or absolute value including unit of measure for the tare check.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.1.4 CONFIGURATION OF SYSTEM-TRIGGERED EXCEPTIONS

6.3.1.4.1 GID-2672038 TARE CHECK CONFIGURATION (SR0720.8.6)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If so, ensure that the **Lower tolerance** and **Upper tolerance** attributes of the **Tare check tolerance definition** process parameter (GID-2672037)are set. If they are not set, 0 is used for the tolerance calculation. Default setting: **No**.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Failed tare check (SR0720.3.2.2)** system-triggered exception (GID-2669976)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.1.4.2 GID-2672039 UNFORESEEN RESUME (SR0720.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Unforessen resume (SR0720.3.2.1)** system-triggered exception (GID-2669978).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.1.5 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

6.3.1.5.1 GID-2672040 REDO ZERO (SR0720.8.2)

Does not apply if scale is configured as manual scale.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Redo zero (SR0720.3.1.2)** user-triggered exception (GID-2669982).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.1.5.2 GID-2672041 RETURN TO MATERIAL MANAGEMENT (SR0720.8.3)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Return to material management (SR0720.3.1.1)** user-triggered exception (GID-2669980).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.1.5.3 GID-2672042 USE OFFLINE TARE (SR0720.8.4)

Does not apply if scale is configured as manual scale.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Use offline tare (SR0720.3.1.3)** user-triggered exception (GID-2669983).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4 Exceptions (SR0720.3+)

The phase supports user-defined, user-triggered (GID-2668560), system-triggered (GID-2668559), and post-completion exceptions (GID-2668561)and their configuration by means of process parameters (GID-2668558).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

6.4.1 System-triggered Exceptions (SR0720.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

6.4.1.1 GID-2669976 Failed tare check (SR0720.3.2.2)

The **Failed tare check** exception is displayed automatically if the check is enabled, but

- no container was not identified with the **O Identify container (SR0750+)** phase (GID-2668073)or
- the container tare is out of the calculated limits or
- the limits cannot be calculated due to missing conversion factors or
- the container's property of the **Reference Tare (RS)** purpose is empty, or
- no property of the **Reference Tare (RS)** purpose has been assigned to the container.

Representation of the exception:

- <Exception text>
  (taken from **Tare check configuration (SR0720.8.6)** process parameter (GID-2672038))
  - If no target container has been identified:
    The container tare is unknown, since no container has been identified yet. Please check the structure of your recipe.
  - If the actual tare does not match the reference tare:
    Tare: <actual tare>
    Reference tare: <reference tare> [<lower limit> .. <upper limit>]
  - Example:
    Actual tare value does not match the stored reference tare defined for the container.
    Check if the container is empty and all accessories have been dismounted.
    Tare: 23 g
    Reference tare: 25 g [24 g .. 25 g]

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.1.2 GID-2669977 Failed tare check - Logic (SR0720.3.2.2.1)

- Trigger: Trigger: Check has failed
- Precondition: Tare check is enabled (**Tare check configuration (SR0720.8.6)** process parameter (GID-2672038))
- Postcondition: Post-completion exception is recorded

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	▪ Phase records the exception. ▪ In the default configuration, the phase neither overwrites the reference tare in the container's property of the **Reference Tare (RS)** purpose with the actual tare nor updates the logbook accordingly (if maintained). See also **Allow Override Reference Tare (SR0720.11.1)** configuration key (GID-2668573).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.1.3 GID-2669978 UNFORESEEN RESUME (SR0720.3.2.1)

Representation of the exception:

- <Exception text>
  (taken from **Unforeseen resume (SR0720.8.5)** process parameter (GID-2672039))
  The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
  Consider to replace the affected position.
  - Example:
    A critical resume situation has occurred. Contact your supervisor before proceeding.
    The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
    Consider to replace the affected position.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.1.4 GID-2669979 UNFORESEEN RESUME - LOGIC (SR0720.3.2.1.1)

- Trigger: Output Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

Step	#	Description
Phase activation	10	Phase displays the **Unforeseen resume (SR0720.3.2.1)** system-triggered exception.
Operator triggers exception	30	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.2 User-triggered Exceptions (SR0720.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

6.4.2.1 GID-2669980 RETURN TO MATERIAL MANAGEMENT (SR0720.3.1.1)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.

Representation during exception handling:

- Instruction:
  Return to material management.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Return to material management (SR0720.8.3)** process parameter (GID-2672041))
  - Example:
    Back to material management.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.2.2 GID-2669981 RETURN TO MATERIAL MANAGEMENT - LOGIC (SR0720.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator confirms exception	10	Phase records the exception.
	20	Phase is completed automatically and returns to **Manage produced material (SR0700+)** phase (GID-2668053).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.2.3 GID-2669982 REDO ZERO (SR0720.3.1.2)

Does not apply if scale is configured as manual scale.

The **Redo zero** exception allows an operator to reset the scale to zero.
The exception is only enabled if the **Zeroing** option is selected in the equipment master data of the current scale.

Representation during exception handling:

- Instruction:
  Repeat zeroing.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Redo zero (SR0720.8.2)** process parameter link)
  - Example:
    Zeroing repeated.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.2.4 GID-2669983 USE OFFLINE TARE (SR0720.3.1.3)

Does not apply if scale is configured as manual scale.

The **Use offline tare** exception allows an operator to enter the offline tare value manually due to a broken scale connection.

Representation during exception handling:

- Instruction:
  Use the offline tare.
  - Only for **Net** and **Gross** weighing methods:
    Input box for tare value.
  - Only for **Pallet** weighing method:
    Container tare, input box.
    Number of containers on pallet, input box.
    Pallet tare, input box.

Confirm button.

- Exception text:
  <Exception text>
  (taken from **Use offline tare (SR0720.8.4)** process parameter (GID-2672042))
  Offline tare: <tare value>
  - Example:
    Offline tare used.
    Offline tare: 0.45 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.2.5 GID-2669984 USE OFFLINE TARE - LOGIC (SR0720.3.1.3.1)

Does not apply if scale is configured as manual scale.

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	For **Net** weighing, operator enters current offline tare value manually. For **Gross** weighing, see **Weighing method - Gross (SR0720.2.4)** function (GID-2669965). For **Pallet** weighing, see **Weighing method - Pallet (SR0720.2.5)** function (GID-2669967).
Operator confirms exception	30	Phase records the exception. Tare value is read-only in the Execution Window. No tare value is communicated to/from scale. Tare type is **Offline**.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

6.5 Information Messages

There are no information messages available.

6.6 Questions (SR0720.3.5+)

Questions are represented in a question dialog containing a message type-specific icon, the question, a **Yes** button, and a **No** button.

The following questions are available to request a decision from the operator how to proceed.

6.6.1 GID-2668562 Tare below valid range (SR0720.3.5.2)

UI text	Comment
The current scale load is below the scale's valid range. Actual load: <scale load (tare weight)> Your scale load must range between <smallest permitted - minimum> and <highest permitted range - maximum> Do you wish to proceed?	This message is not displayed if at the same time the tare value triggers the display of the **Tare equals zero (SR0720.3.5.1)** question (GID-2668563). Message pack: wd_Tare<version> Message ID: tareBelowValidRange_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.6.2 GID-2668563 Tare equals zero (SR0720.3.5.1)

UI text	Comment
The tare is 0. Do you wish to proceed?	Message pack: wd_Tare<version> Message ID: nullTare_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.7 Decisions

There are no decisions available.

6.8 Error Messages (SR0720.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

6.8.1 GID-2668564 Scale online error (SR0720.3.6.1)

UI text	Comment
A scale communication error has occurred at the <scale> scale.	Message pack: wd_UIMessage<version> Message ID: scalesCommunication_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.8.2 GID-2668565 Wrong scale (SR0720.3.6.2)

UI text	Comment
You have scanned another scale than selected. Scan the previously selected scale to proceed.	Message pack: wd_UIMessage<version> Message ID: WrongScale_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.8.3 GID-2668566 Negative tare (SR0720.3.6.3)

UI text	Comment
Cannot proceed with the current negative tare. Make sure the scale is still correctly loaded with the tared container. If the scale is empty, repeat zeroing and tare again.	Message pack: wd_Tare<version> Message ID: negativeTare_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.8.4 GID-2668567 Scale driver error (SR0720.3.6.4)

UI text	Comment
Cannot obtain a stable reading or a scale communication error has occurred. Please try again.	Message pack: srv_eqm.WDEquipmentService Message ID: tareWeighedFailed Message ID: errorDuringTareClear_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.8.5 GID-2668568 Tare above valid range (SR0720.3.6.5)

UI text	Comment
Cannot tare, since the current scale load is above the scale's valid range, which may have been determined by the required scale resolution. Current scale load: <scale load (tare weight)> Your scale load must range between <smallest permitted - minimum> and <highest permitted range - maximum>	Message pack: wd_Tare<version> Message ID: scaleNotSuitableForTare_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.9 Output Variables (SR0720.9+)

The following output variables are available to reference the phase's output.

6.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

6.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

6.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

6.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

6.10 Configuration Keys (SR0720.11+)

The following configuration keys are available to configure the phase's behavior.

6.10.1 GID-2668573 Allow override reference tare (SR0720.11.1)

- **Phase/OWTare/allowOverrideReferenceTare**
- **Type**: Boolean
- **Value**: False
- **Description**: The configuration applies to the **Failed tare check** system-triggered exception of the **O Tare** phase.
  For details, see **Failed Tare Check (SR0720.3.2.2)** system-triggered exception (GID-2669976).
  If the value is set to **true** and the check fails, the operator first has to sign the exception then the phase overwrites the existing reference tare in the container's property of the **Reference Tare (RS)** purpose with the actual tare and updates the logbook accordingly (if maintained).
- **Evaluated**: When the **O Tare** phase is started in the Production Execution Client.
- **Range**: [False, True]

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7 Weigh Phase (SR0730+)

The **Weigh** phase (O Weigh) allows an operator to record the actual weight of a target container or sublot and to print a label for it. Additionally, an operator can prepare an empty container or sublot for weighing material in a later run of the Output Weighing loop.

It displays a scale control (not in **Prepare only** mode) with real-time interfacing to the selected scales and communicates all information between the scale and its operators. The scale control displays the actual value of the item that is being processed and the valid weighing range of the selected scale. The operator confirms a weighing value by scanning the barcode of the scale.
If a scale is used that is configured as manual scale or if the **Quantity entry** weighing method is used, the weighing range is displayed without a scale control. The phase requires a manual entry of the weighing value and for a manual scale its meaning (**Net scale value** or **Gross scale value**).
If an empty target container has been identified or prepared, the **Weigh** phase supports the maintenance of the container's life cycle and sets the container's properties of the **Current Tare (RS)** and **Current Sublot (RS)** purposes.
In case of a loaded scale, it maintains the scale's property of the **Current Load (RS)** purpose.
Details of the weighing process are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report.
Anomalies that occur during processing are covered by the phase exception handling (e.g. overweight, underweight, reprint of labels).
After completion the phase displays the registered weight, both in the Execution Window and in the Navigator. Additionally, the Navigator displays a button that shows the identifier of the prepared or weighed sublot and provides access to the post-completion exception.

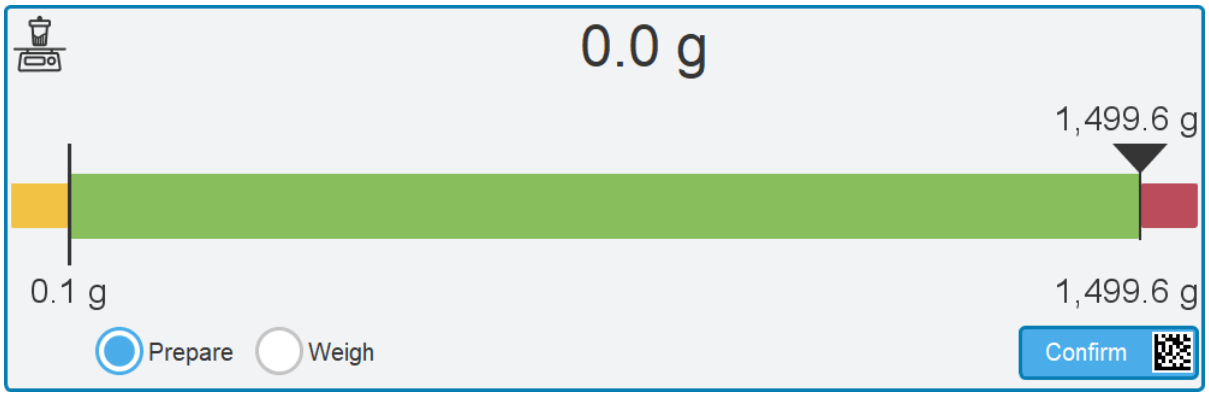

Figure 17: Weigh during execution (Prepare)

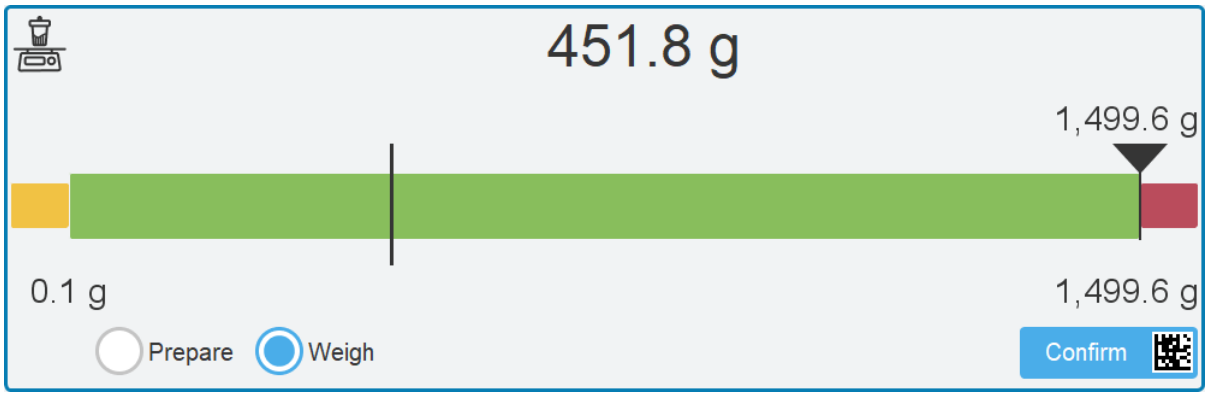

Figure 18: Weigh during execution (Prepare)

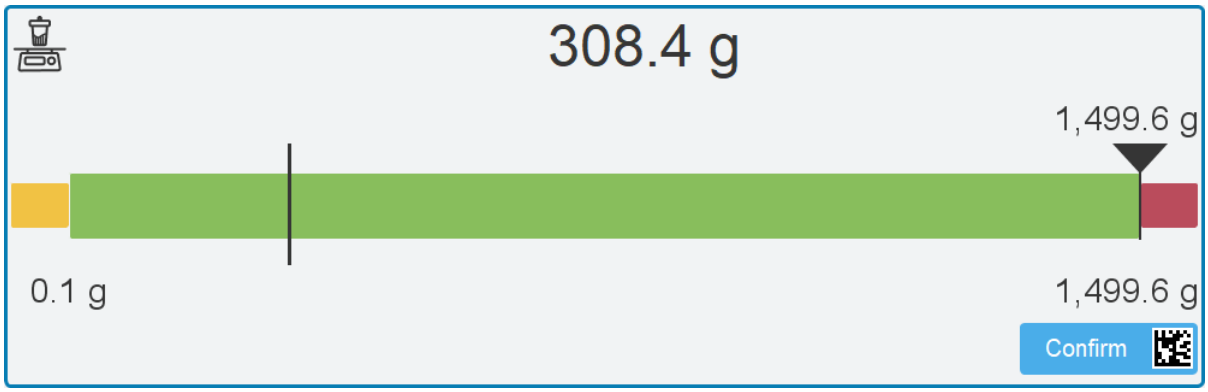

Figure 19: Weigh during execution (Prepare)

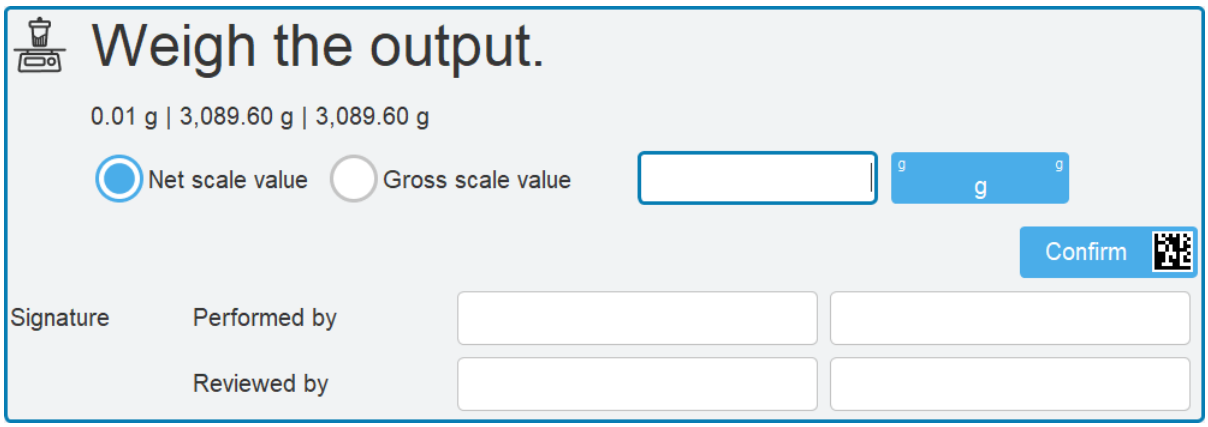

Figure 20: Weigh during execution (Prepare)

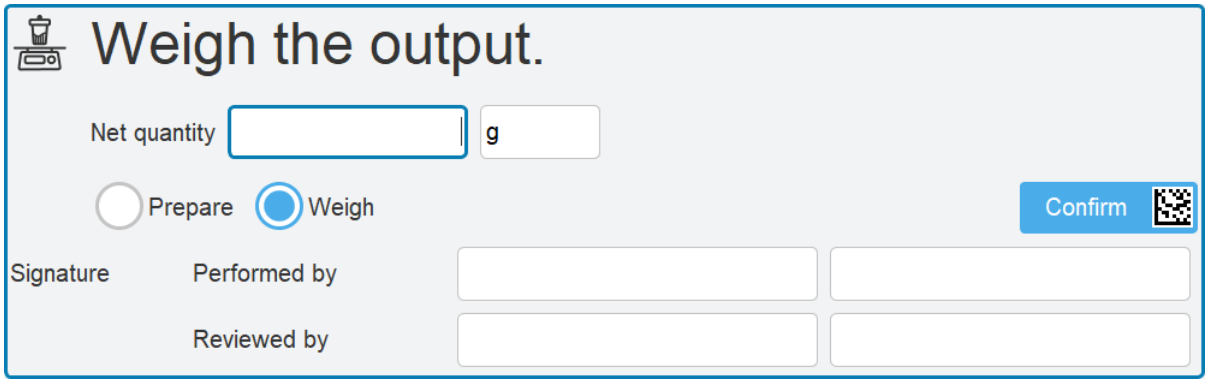

Figure 21: Weigh during execution (Prepare)

7.1 Layout

The phase provides individual layouts for its representation during execution (GID-2668574), in the Navigator (GID-2668575), and in the sub-report (GID-2668576).

7.1.1 Representation during Execution (SR0730.1+)

The representation during execution depends on the phase mode.

7.1.1.1 GID-2669985 Preview mode (SR0730.1.1)

1. Phase-specific icon.
2. <Instruction text>
   (taken from **Instruction (SR0730.8.1)** process parameter (GID-2672047))
3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.2 GID-2669986 Active mode (SR0730.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Scale value>
4. Scale control with actual value and tolerance band (linear scale mode)
   - Only if a target weight is defined: Scale control with target weight, actual, and tolerance values and marker for upper range of scale.
5. **Prepare** option button (default) and **Weigh** option button.>
   - Only for **Pallet** weighing and if a prepared sublot is weighed: No option buttons are displayed (Default is **Weigh**).

- The phase is completed automatically, if the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).

6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.3 GID-2669987 ACTIVE MODE (MANUAL SCALE) (SR0730.1.6)

This representation applies to all weighing methods if the selected scale is configured as manual scale.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0730.8.1)** process parameter (GID-2672047))
4. Tolerance values.
5. **Net scale value** option button and **Gross scale value** option button.
6. Input box and **UoM** toggle button.
   - The **UoM** toggle button provides all UoMs that are supported by the manual scale.
7. **Prepare** option button (default) and **Weigh** option button.
   - Only for **Pallet** weighing and if a prepared sublot is weighed: No option buttons are displayed (Default is **Weigh**).
   - The phase is completed automatically, if the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
8. Phase completion signature panel
   - **WD_ES_MANUAL_SCALE** access privilege.
9. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.4 GID-2669988 ACTIVE MODE (QUANTITY ENTRY) (SR0730.1.7)

This representation applies to the **Quantity entry** weighing method.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0730.8.1)** process parameter (GID-2672047))
4. Input box for the quantity.
5. Input box for the unit of measure.
   - The unit of measure of the planned quantity and all convertible UoMs are allowed. The input box is pre-filled with the unit of measure of the planned quantity.
   - If the **Planned quantity mode** is set to **None**, the unit of measure of the material and all convertible UoMs are allowed. The input box is pre-filled with the unit of measure of the material.
6. **Prepare** option button (default) and **Weigh** option button.
   - The phase is completed automatically, if the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
7. Phase completion signature panel
   - **WD_ES_QUANTITY_ENTRY_O** access privilege.
8. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.5 GID-2669989 ACTIVE MODE (PREPARE ONLY) (SR0730.1.4)

Only in case the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)):

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. Weight

4. 0 <UoM of tare value>
   - <UoM of the planned quantity or material> if the **Quantity entry** weighing method is used.
5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.6 GID-2669990 COMPLETED MODE (SR0730.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. Weight
4. <Weighing value>
5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.7 GID-2669991 COMPLETED MODE (PREPARE ONLY) (SR0730.1.5)

Only in case the **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)):

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. Weight
4. 0 <UoM of tare value>
   - <UoM of the planned quantity or material> if the **Quantity entry** weighing method has been used.
5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.2 Representation in Navigator (SR0730.4+)

The Navigator provides the following details:

7.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:
    Weigh Material

7.1.2.2 GID-2669993 INFORMATION COLUMN (SR0730.4.1)

- <Weighing value>
  - Example:
    23.45 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.2.3 GID-2669994 ACTION COLUMN (SR0730.4.2)

- <Sublot identifier>, reprints the sublot label.
  - Example:
    SL00001234
  - Only for **Pallet** weighing with more than one sublot:
  - Sublots, provides reprint exceptions for each sublot label.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.3 Representation in Sub-report (SR0730.5+)

The sub-report contains the following information:

7.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

7.1.3.2 GID-2669996 SUB-REPORT ELEMENTS (SR0730.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Position: <number>
- Target sublot: <number>
- Actual quantity: <weighing value>
- Additionally if the scale is configured as manual scale:
  - Manual scale
  - Net scale value entered (if applicable)
  - Gross scale value entered (if applicable)
- Additionally for **Pallet** weighing:
  - <List of target sublot identifiers>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2 Business Logic (SR0730.2+)

The phase implements the following business logic.

7.2.1 Main Path

Business logic related to the main path:

7.2.1.1 GID-2669997 ACTIVATE SCALE CONTROL (SR0730.2.1)

Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.
See **Weigh (Manual Scale) (SR0730.2.4)** function (GID-2669998), **Weighing Method - Quantity Entry (SR0730.2.12)** function (GID-2670004).

- Function: Activation of scale control
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: N/A

Step	#	Description
Phase activation	10	Phase establishes communication to scale.
	20	▪ If no target weight is defined: Phase displays scale control in linear mode. Begin of tolerance band = scale resolution, end of tolerance band / nominal value = upper value of scale range – actual tare – scale resolution. ▪ If a target weight is defined: Phase displays scale control with target weight and its lower and upper tolerances. The actual tolerances are calculated based on the tolerance values derived from the recipe definition and the resolution of the scale: Lower tolerance = round up according to scale resolution (nominal - lower tolerance value (recipe) + scale resolution) Upper tolerance = round down according to scale resolution (nominal + upper tolerance value (recipe) – scale resolution)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.1.2 GID-2669998 WEIGH (MANUAL SCALE) (SR0730.2.4)

Applies only if scale is configured as manual scale.

- Function: Weighing with a scale that is configured as manual scale
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: N/A

Step	#	Description
Phase activation	10	Phase displays the **Active mode (manual scale) (SR0730.1.6)** layout (GID-2669987). ▪ If no target weight is defined: Begin of tolerance band = scale resolution, end of tolerance band / nominal value = upper value of scale range – actual tare – scale resolution.

Step	#	Description
		▪ If a target weight is defined: Phase displays target weight and its lower and upper tolerances. The actual tolerances are calculated based on the tolerance values derived from the recipe definition and the resolution of the scale: Lower tolerance = round up according to scale resolution (nominal - lower tolerance value (recipe) + scale resolution) Upper tolerance = round down according to scale resolution (nominal + upper tolerance value (recipe) – scale resolution) In case of **Net** weighing, the **Net scale value** option button is selected per default. In case of **Gross** weighing or **Pallet** weighing, the **Gross scale value** option button is selected per default.
	20	Operator enters current scale value manually.
Phase completion signature	30	Pre-defined phase completion signature is requested according to the **WD_ES_MANUAL_SCALE** access privilege. Any other phase completion signature that has been assigned to the phase is ignored.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.1.3 GID-2669999 PREPARE ONLY MODE (SR0730.2.8)

- Function: Phase operates in **Prepare only** mode
- Type: Main path
- Precondition: **Operation mode** of the **Manage produced material** phase is set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase prints a label.
	20	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.1.4 GID-2670000 CONFIRM WEIGHT BY SCAN (SR0730.2.2)

Does not apply if the **Quantity entry** weighing method is used.

- Function: Confirmation of weight by use of barcode scan
- Type: Main path
- Trigger: Operator confirms final weight that has been placed on the scale
- Postcondition: N/A

Step	#	Description
Operator scans scale	5	Phase reads scanned data.
	10	▪ If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading. ▪ If barcode reading was technically not successful, phase remains in listening mode.
	20	If barcode does not correspond to the identifier of the selected scale, phase displays the **Wrong scale (SR0730.3.6.2)** error message (GID-2668586).
	25	Only if PharmaSuite is configured to communicate with Warehouse Management and a warehouse-related error has occurred during the last **Finalize target sublot (SR0730.2.5)** function (GID-2670002), phase can only be completed when the **Warehouse error (SR0730.3.1.5)** user-triggered exception (GID-2670027)has been recorded. If the exception is not recorded, phase displays the **Missing warehouse exception recording (SR0730.3.6.9)** error message link.
	30	▪ Does not apply if scale is configured as manual scale. If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the **Scale driver error (SR0730.3.6.3)** error message (GID-2668587).
	40	Phase reads and records scale value.

Step	#	Description
	50.1	If the weighing mode is active (**Weigh** option button is selected or already prepared sublot is weighed) and the scale value is greater than zero, phase continues with the **Finalize target sublot (SR0730.2.5)** function (GID-2670002).
	50.2	If the preparation mode is active (**Prepare** option button is selected or operation is used for **Prepare only**) and the scale value is equal to zero, phase continues with the **Finalize target sublot (SR0730.2.5)** function (GID-2670002).
	50.3	If the scale value does not correspond to the weighing or preparation mode of the phase, phase displays the **Weighing value not allowed (SR0730.3.6.6)** error message (GID-2668589).
	50.4	If a target weight is defined and the scale value is less than the lower tolerance or greater than the upper tolerance, phase creates the **Out of tolerance (SR0730.3.2.3)** system-triggered exception (GID-2670001).
	50.5	If a target weight is defined and the scale value is greater than lower tolerance and less than upper tolerance, phase continues with the **Finalize target sublot (SR0730.2.5)** function (GID-2670002).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.1.5 GID-2670001 Confirm weight by button (SR0730.2.3)

- Function: Confirmation of weight by use of button
- Type: Main path
- Trigger: Operator confirms final weight that has been placed on the scale
- Postcondition: N/A

Step	#	Description
Operator confirms weight	5	Only if PharmaSuite is configured to communicate with Warehouse Management and a warehouse-related error has occurred during the last **Finalize target sublot (SR0730.2.5)** function (GID-2670002), phase can only be completed when the **Warehouse error (SR0730.3.1.5)** user-triggered exception (GID-2670027)has been recorded. If the exception is not recorded, phase displays the **Missing warehouse exception recording (SR0730.3.6.9)** error message (GID-2668592).

Step	#	Description
	10	▪ Does not apply if the **Quantity entry** weighing method is the default weighing method. If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the **Scale driver error (SR0240.3.6.3)** error message (GID-2669091).
	20	Phase reads and records scale value.
	30.1	If the weighing mode is active (**Weigh** option button is selected or already prepared sublot is weighed) and the scale value is greater than zero, phase continues with the **Finalize target sublot (SR0730.2.5)** function (GID-2670002)).
	30.2	If the preparation mode is active (**Prepare** option button is selected or operation is used for **Prepare only**) and the scale value is equal to zero, phase continues with the **Finalize target sublot (SR0730.2.5)** function (GID-2670002).
	30.3	If the scale value does not correspond to the weighing or preparation mode of the phase, phase displays the **Weighing value not allowed (SR0730.3.6.6)** error message (GID-2668589).
	30.4	If a target weight is defined and the scale value is less than the lower tolerance or greater than the upper tolerance, phase creates the **Out of tolerance (SR0730.3.2.3)** system-triggered exception (GID-2670019)
	30.5	If a target weight is defined and the scale value is greater than lower tolerance and less than upper tolerance, phase continues with the **Finalize target sublot (SR0730.2.5)** function (GID-2670002).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.1.6 GID-2670002 FINALIZE TARGET SUBLOT (SR0730.2.5)

- Function: Finalization of target sublot
- Type: Main path
- Trigger: Weight is confirmed
- Postcondition: Phase is completed

Step	#	Description
Function finalization	10	▪ For **Net** or **Gross** weighing, phase prints container label(s) with tare and net weight. ▪ For **Quantity entry**, phase prints container label(s) with net weight. ▪ For **Pallet** weighing, see **Weighing method - Pallet (SR0730.2.7)** function (GID-2670003) ▪ **Sublot identifiers (SR0730.9.3)** output variable link contains the identifier(s) of the sublot (s).
	20	Phase calculates the use-by date for the target sublot based on the **Use-by date (SR0730.8.2)** process parameter (GID-2672048),
	30	If the **Prepare** option button is selected, the status of the sublot position is set to **Prepared**. If a phase completion signature is assigned to the phase, the signature is ignored during execution. Phase is completed automatically.
	40	If the **Weigh** option button is selected, the status of the sublot position is set to **Recorded** and the phase is completed automatically. ▪ If a phase completion signature is assigned, the signature is requested and the phase is completed upon manual confirmation. ▪ If no sublots of the ingoing material have been identified for this order step, phase displays the **No ingoing material defined (SR0730.3.6.7)** error message (GID-2668590).
	50	In case no batch has been created for the output material yet, a new batch is created automatically and the batch status is set to **Quarantined**.

Step	#	Description
	55	If the preparation mode is active (**Prepare** option button is selected or operation is used for **Prepare only**): ▪ No CCT TITR inheritance is performed. ▪ The TITR counters of the sublot are not updated. If the **Weigh** option button is selected (sublot is not prepared): ▪ According the inheritance rule configuration at target sublot's material (part), the CCT TITR values are calculated with **Worst Case Inheritance Rule** or **No Inheritance Rule** (see (GID-3632063) and (GID-3695977) in Functional Requirement Specification Execution Framework [A1] (GID-2668043)) and set when the sublot is created. If an already prepared sublot is weighed: ▪ According the inheritance rule configuration at target sublot's material (part), the CCT TITR values are calculated with **Worst Case Inheritance Rule** or **No Inheritance Rule** (see (GID-3632063) and (GID-3695977) in Functional Requirement Specification Execution Framework [A1] (GID-2668043)). ▪ In case of **Worst Case Inheritance Rule**, the TITR values of the prepared sublot are only updated if the calculated values are worse than the existing cumulated time of a sublot's TITR counter.
	60	Only if PharmaSuite is configured to communicate with Warehouse Management: In case a warehouse-related error has occurred, phase displays the **Warehouse error (SR0730.3.6.8)** error message (GID-2668591). The phase can only be completed when the **Warehouse error (SR0730.3.1.5)** user-triggered exception (GID-2670027)has been recorded.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.2 Weighing Method-specific Paths

Business logic related to weighing methods:

7.2.2.1 GID-2670003 Weighing method - Pallet (SR0730.2.7)

- Function: Use of **Pallet**
- Type: Special handling of weighing methods other than **Net** weighing
- Precondition: **Operation mode** of the **Manage produced material** phase is not set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
  Sublot must not be identified.

- Trigger: Specific weighing method is selected
- Postcondition: N/A

Step	Description
Phase activation	For **Pallet** weighing, the **Prepare** option button is not available.
Finalize target sublot (SR0730.2.5) function (GID-2670002)	Phase prints a label for each sublot with number of containers (e.g.: 1/3, 2/3, 3/3), average tare, average net value per container, and total net weight of all containers.
	Phase extends representation in the sub-report to the **Sub-report elements (SR0730.5.1)** layout (GID-2669996).
	Phase adds the **Reprint label (SR0730.3.3.1)** post-completion exception (GID-2670029)to the **Action column (SR0730.4.2)** in the Navigator (GID-2669994).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.2.2 GID-2670004 Weighing method - Quantity entry (SR0730.2.12)

- Function: Use of **Quantity entry**
- Type: Special handling of weighing methods other than **Net** weighing
- Precondition: **Operation mode** of the **Manage produced material** phase is not set to **Prepare only** (see **Operation mode (SR0700.8.12)** process parameter (GID-2671996)).
- Trigger: Specific weighing method is selected
- Postcondition: N/A

Step	Description
Phase activation	Phase displays the **Active mode (Quantity entry) (SR0730.1.7)** layout link.
	Operator enters current quantity manually.
	Pre-defined phase completion signature is requested according to the **WD_ES_QUANTITY_ENTRY_O** access privilege. Any other phase completion signature that has been assigned to the phase is ignored.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.2.3 GID-2670005 TARGET SUBLOT STATUS (SR0730.2.13)

- Function: Inherit sublot status from source sublot to the target sublot
- Type: Main path
- Trigger: Target sublot creation
- Postcondition: N/A

Step	#	Description
Target sublot is created (Prepare only or Weigh mode)	10	The target sublot status is set to the value defined as target sublot status with the material output parameter.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.3 Equipment Management

Business logic related to equipment management:

7.2.3.1 GID-2670006 CONTAINER MANAGEMENT (SR0730.2.10)

- Function: Manage container
- Type: Special handling of sublot assignment and container status
- Precondition: Container must be of the **Container (RS)** equipment type
- Trigger: Empty or prepared target container has been identified during Output Weighing
- Postcondition: Container's property of the **Current Sublot (RS)** and **Current Tare (RS)** purposes is maintained and container status is managed

Step	Description
Case: An empty target container has been identified and the phase operates in the **Prepare only** mode or the **Prepare** option button has been selected (see **Manage produced material (SR0700+)** phase (GID-2668053)).	▪ In deviation from the **Prepare only mode (SR0730.2.8)** function (GID-2669999), phase does not create a sublot and does not print a label. ▪ In deviation from the **Finalize target sublot (SR0730.2.5)** function (GID-2670002), phase sets the status of the container position to **Prepared**. ▪ Phase writes a prepared container's property of the **Current Tare (RS)** purpose. ▪ No trigger is performed. ▪ No unbind is performed. ▪ **Target container ID (SR0730.9.2)** output variable (GID-2668599)contains the identifier of the target container object. ▪ **Target container (SR0730.9.4)** output variable (GID-2668598)contains the target container object.
Case: Weighing of a prepared target container.	▪ Phase creates a sublot. ▪ Phase updates the prepare container's property of the **Current Sublot (RS)** purpose. ▪ The tare of the sublot is updated with the container's property value of the **Current Tare (RS)** purpose. ▪ Phase sends **CONT_LOAD** trigger to the graph of the **Container Cleaning (RS)** purpose. In case the target container is an equipment group, the trigger is sent to the equipment group. ▪ Phase resets binding context and unbinds container. In case the target container is an equipment group, the unbinding is performed for each equipment entity of the equipment group. ▪ Phase prints a label. ▪ **Target container ID (SR0730.9.2)** output variable (GID-2668599)contains the identifier of the target container object. ▪ **Target container (SR0730.9.4)** output variable (GID-2668598)contains the target container object. ▪ **Sublot identifiers (SR0730.9.3)** output variable (GID-2668600)contains the identifier of the sublot.

Step	Description
Case: An empty target container has been identified and is weight directly (without preparation).	▪ Phase creates a sublot. ▪ Phase updates the prepared container's property of the **Current Tare (RS)** and **Current Sublot (RS)** purposes. ▪ The tare of the sublot is updated with the container's property value of the **Current Tare (RS)** purpose. ▪ Phase sends **CONT_LOAD** trigger to the graph of the **Container Cleaning (RS)** purpose. In case the target container is an equipment group, the trigger is sent to the equipment group. ▪ Phase resets binding context and unbinds container. In case the target container is an equipment group, the unbinding is performed for each equipment entity of the equipment group. ▪ Phase prints a label. ▪ **Target container ID (SR0730.9.2)** output variable (GID-2668599)contains the identifier of the target container object. ▪ **Target container (SR0730.9.4)** output variable (GID-2668598)contains the target container object. ▪ **Sublot identifiers (SR0730.9.3)** output variable (GID-2668600)contains the identifier of the sublot.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.3.2 GID-2670007 SCALE MANAGEMENT (SR0730.2.11)

Does not apply if the **Quantity entry** weighing method is used.

- Function: Manage scales
- Type: Special handling of scale properties
- Precondition: Scale must be of the **Scale (RS)** equipment type
- Postcondition: Scale properties are maintained

Step	Description
Case: Phase is completed.	▪ Phase writes or clears the scale's runtime property of the **Current Load (RS)** purpose according to the **Keep scale loaded (SR0730.8.5)** process parameter (GID-2672049). ▪ In case of **Keep scale loaded** is set to **Yes**, the identifier of the prepared container or prepared sublot is written to the **Current Load (RS)**-related property. ▪ In case of **Keep scale loaded** is set to **No**, the **Current Load (RS)**-related property is cleared.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3 Recipe Parameters

The phase provides material output parameters as process outputs (GID-2668580)and process parameters (GID-2668581).

7.3.1 Process Outputs (SR0730.7+)

7.3.1.1 GID-2670008 Material output parameters (SR0730.7.1)

The default material output parameter is available to define which material can be managed during execution.
Quantity definitions of the material output parameter are populated to the **Table of materials (SR0700.1.4)** list (GID-2669856)that is displayed during execution of the **Manage produced material (SR0700+)** phase (GID-2668053)This includes the reflection of quantity-related calculations during order explosion.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2 Process Parameters (SR0730.8+)

The following process parameters define the behavior of the phase.

7.3.2.1 Instruction Table-specific Parameters

7.3.2.1.1 Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

7.3.2.1.2 Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

7.3.2.2 Instruction Link-specific Parameters

7.3.2.2.1 Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2672046). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

7.3.2.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

7.3.2.3 BASIC PARAMETERS

7.3.2.3.1 GID-2672047 INSTRUCTION (SR0730.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.3.2 GID-2672048 USE-BY DATE (SR0730.8.2)

Attribute	Type	Comment
Use-by date [days]	Numeric	Defines the number of days allowed between the creation of an intra material sublot and its use in further processing steps. If the evaluation of the use-by date is required during further processing, the respective phase capabilities need to be adapted.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.3.3 GID-2672049 KEEP SCALE LOADED (SR0730.8.5)

Does not apply if the **Quantity entry** weighing method is used.

Attribute	Type	Comment
Enabled	Boolean	Controls if the scale retains its "loaded" status during the subsequent process or if the "loaded" status is reset. While "loaded", the scale is not zeroed during scale selection and a release scale check is skipped.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.4 Configuration of System-triggered Exceptions

7.3.2.4.1 GID-2672050 Unforeseen resume (SR0730.8.10)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Unforeseen resume (SR0730.3.2.2)** system-triggered exception (GID-2670015).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.4.2 GID-2672051 Status transition failed (SR0730.8.9)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Status transition failed (SR0730.3.2.1)** system-triggered exception (GID-2670017).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.4.3 GID-2672052 TOLERANCE CHECK CONFIGURATION (SR0730.8.11)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Out of tolerance (SR0730.3.2.3)** system-triggered exception (GID-2670019).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.5 Configuration of User-triggered Exceptions

7.3.2.5.1 GID-2672053 Override use-by date (SR0730.8.3)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override use-by date (SR0730.3.1.4)** user-triggered exception (GID-2670025).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.5.2 GID-2672054 Enter weight manually (SR0730.8.4)

Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Enter weight manually (SR0730.3.1.2)** user-triggered exception (GID-2670023).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.5.3 GID-2672055 RETURN TO MATERIAL MANAGEMENT (SR0730.8.6)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Return to material management (SR0730.3.1.1)** user-triggered exception (GID-2670021).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.5.4 GID-2672056 WAREHOUSE ERROR (SR0730.8.12)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

This process parameter requires that PharmaSuite is configured to communicate with Warehouse Management.

See also **Warehouse error (SR0730.3.1.5)** user-triggered exception (GID-2670027).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.6 CONFIGURATION OF POST-COMPLETION EXCEPTIONS

7.3.2.6.1 GID-2672057 REPRINT LABEL (SR0730.8.8)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Reprint label (SR0730.3.3.1)** post-completion exception (GID-2670029).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.4 Exceptions (SR0730.3+)

The phase supports user-defined, user-triggered (GID-2668583), system-triggered (GID-2668582), and post-completion exceptions (GID-2668584)and their configuration by means of process parameters (GID-2668580).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

7.4.1 System-triggered Exceptions (SR0730.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

7.4.1.1 GID-2670015 Unforeseen resume (SR0730.3.2.2)

Representation of the exception:

- <Exception text>
  (taken from **Unforeseen resume (SR0730.8.10)** process parameter (GID-2672050))
  The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
  Consider to replace the affected position.
  - Example:
    A critical resume situation has occurred. Contact your supervisor before proceeding.
    The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
    Consider to replace the affected position.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.1.2 GID-2670016 UNFORESEEN RESUME - LOGIC (SR0730.3.2.2.1)

- Trigger: Output Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

Step	#	Description
Phase activation	10	Phase displays the **Unforeseen resume (SR0730.3.2.2)** system-triggered exception.
Operator triggers exception	30	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.1.3 GID-2670017 STATUS TRANSITION FAILED (SR0730.3.2.1)

The **Status transition failed** exception is displayed automatically if a certain status transition could not be performed based on the given graph purpose and trigger.

In case the trigger was executed on a container and the container is an equipment group, multiple failed transitions on different entities can be reported combined in one exception.

The potential reasons for a failed status transition are:

- The graph of the required purpose is missing.
- The trigger is missing.
- Source status does not match.
- Condition cannot be fulfilled or is not unique (in case of multiple transition definitions per trigger).
- Error during condition evaluation.
- Error during action evaluation.

Representation of the exception:

Exception dialog

- <Exception text>
  (taken from **Status transition failed (SR0730.8.9)** process parameter (GID-2672051))
  <the reason that applies>
- List of potential reasons:
  - The graph of the required purpose is missing.
  - The trigger you are trying to perform is not contained in the graph.
  - Cannot find a transition for the current status.
  - Cannot find a fulfillable transition condition for the current status.
  - There is more than one fulfillable transition condition available for the current status: <TR-ID; TR-ID; ...>.
  - Cannot evaluate the transition condition (<TR-ID>).
  - Cannot evaluate the transition action (<TR-Action ID>) from the current status to the new status (<display text (key)>).

Exception Window

- <Exception text>
  (taken from **Status transition failed (SR0730.8.9)** process parameter (GID-2672051))
  <reason>
  Equipment: <equipment identifier> / <equipment short description>
  Equipment type: <list of equipment types> (if available)
  Graph (ID): <graph display text> (<identifier>)
  Purpose: <purpose>
  Current status (key): <display text> (<key>)
  Failed trigger (key): <display text> (<key>)
  - Example:
    Status transition failed.
    Cannot find a transition for the current status.
    Equipment: IBC0033
    Equipment type: Container (RS)
    Graph (ID): IBC Cleaning (IBCCleaning01)
    Purpose: Container Cleaning (RS)
    Current status (key): Blocked (BLOCKED)
    Failed trigger (key): In use (IN_USE)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.1.4 GID-2670018 STATUS TRANSITION FAILED - LOGIC (SR0730.3.2.1.1)

- Trigger: The status transition could not be performed based on the given graph purpose and trigger.
- Postcondition: Phase is active

Step	#	Description
Operator accepts exceptional situation	10	Phase shows exception description to be signed.
Operator signs exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.1.5 GID-2670019 OUT OF TOLERANCE (SR0730.3.2.3)

The **Out of tolerance** exception is displayed automatically if the confirmed weight is outside of the range defined by the target weight tolerances.

Representation of the exception:

- <Exception text>
  (taken from **Tolerance check configuration (SR0730.8.11)** process parameter (GID-2672052))
  Weighing result: Out of tolerance (according to the **Confirm weight by scan (SR0730.2.2)** function (GID-2670000)or **Confirm weight by button (SR0730.2.3)** function (GID-2670001))
  Target weight: <target weight> [<lower limit> .. <upper limit>]
  Actual quantity: <weighing value>
  - Example:
    Tolerance check failed.
    Weighing result: Out of tolerance
    Target weight: 25.00 kg [24.50 kg .. 25.00 kg]
    Actual quantity: 23.56 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.1.6 GID-2670020 Out of tolerance - Logic (SR0730.3.2.3.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator confirms and signs exception	10	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2 User-triggered Exceptions (SR0730.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

7.4.2.1 GID-2670021 Return to material management (SR0730.3.1.1)

The **Return to material management** exception allows an operator to step out of the regular Output Weighing process and start a new run with processing the **Manage produced material** phase.

Representation during exception handling:

- Instruction:
  Return to material management.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Return to material management (SR0730.8.6)** process parameter (GID-2672055)
- Example:
  Back to material identification.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.2 GID-2670022 Return to material management - Logic (SR0730.3.1.1.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator confirms exception	10	Phase records the exception.
	20	Phase is completed automatically and returns to **Manage produced material (SR0700+)** phase (GID-2668053).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.3 GID-2670023 ENTER WEIGHT MANUALLY (SR0730.3.1.2)

Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

The **Enter weight manually** exception allows an operator to enter the weighing value manually. It covers incidents when the communication to the selected scale is interrupted.

Representation during exception handling:

- Instruction:
  Enter the weight manually.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Enter weight manually (SR0730.8.4)** process parameter (GID-2672054))
  Weight: <weighing value>
  - Example:
    Weight entered manually.
    Weight: 34.12 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.4 GID-2670024 ENTER WEIGHT MANUALLY - LOGIC (SR0730.3.1.2.1)

Does not apply if scale is configured as manual scale or if the **Quantity entry** weighing method is used.

Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters current scale value manually. Phase performs checks at phase confirmation.
Operator confirms exception	30	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.5 GID-2670025 OVERRIDE USE-BY DATE (SR0730.3.1.4)

Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

The **Override use-by date** exception allows an operator to override the use-by date calculated from the period defined in the **Use-by date (SR0730.8.2)** process parameter (GID-2672048).

Representation during exception handling:

- Instruction:
  Override.
  Current use-by date <date>
  New use-by date
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Override use-by date (SR0730.8.3)** process parameter (GID-2672053))
  Old use-by date: <date>
  New use-by date: <date>

- Example:
  Use-by date overridden.
  Old use-by date: 12/4/2012
  New use-by date: 12/4/2013

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.6 GID-2670026 Override use-by date - Logic (SR0730.3.1.4.1)

Does not apply if, in the **Prepare only** mode, no sublot of ingoing material (order step input) has been identified yet.

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
Operator confirms exception	20	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.7 GID-2670027 Warehouse error (SR0730.3.1.5)

With the **Warehouse error** exception, an operator can document that a warehouse-related error has occurred.

The exception is only enabled when a warehouse-related error has occurred:

- **Warehouse error (SR0730.3.6.8)** error message (GID-2668591)

Representation of the exception:

- Instruction:
  Confirm to record the warehouse error.
  Confirm button.

- <Exception text>
  (taken from **Warehouse error (SR0730.8.12)** process parameter (GID-2672056))
  A warehouse error has occurred while completing the position.
  <Error message from the warehouse system>
  - Example:
    Document warehouse error
    A warehouse error has occurred while completing the position.
    <Error message from the warehouse system>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.8 GID-2670028 WAREHOUSE ERROR - LOGIC (SR0730.3.1.5.1)

- Trigger: Exception is selected
- Postcondition: N/A

Step	#	Description
Operator triggers exception	10	Phase records the exception according to the **Warehouse error (** (GID-2672056)**)** process parameter link and completes automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.3 Post-completion Exceptions (SR0730.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

7.4.3.1 GID-2670029 REPRINT LABEL (SR0730.3.3.1)

The **Reprint label** exception allows an operator to reprint a sublot label from the Navigator after the completion of the phase. For **Pallet** weighing with more than one sublot, the phase provides exceptions for each sublot label.

Representation during exception handling:

- Instruction:
  Reprint the sublot label.
  <Sublot ID>.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Reprint label (SR0730.8.8)** process parameter (GID-2672057))
  <Sublot identifier> / <batch identifier> / <material identifier> / <material short description>
  - Example:
    Label reprinted.
    SL00001234 / BX123 / D001-03 / Aqua purificata

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.3.2 GID-2670030 Reprint label - Logic (SR0730.3.3.1.1)

- Trigger: Phase is completed, a label has been printed before
- Postcondition: Label has been reprinted

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	20	Phase reprints label.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.5 Information Messages

There are no information messages available.

7.6 Questions

There are no questions available.

7.7 Decisions

There are no decisions available.

7.8 Error Messages (SR0730.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

7.8.1 GID-2668585 Scale online error (SR0730.3.6.1)

UI text	Comment
A scale communication error has occurred at the <scale> scale.	Message pack: wd_UIMessage<version> Message ID: scalesCommunication_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.2 GID-2668586 Wrong scale (SR0730.3.6.2)

UI text	Comment
You have scanned another scale than selected. Scan the previously selected scale to proceed.	Message pack: wd_UIMessage<version> Message ID: WrongScale_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.3 GID-2668587 Scale driver error (SR0730.3.6.3)

UI text	Comment
Cannot obtain a stable reading or a scale communication error has occurred. Please try again.	Message pack: srv_eqm.WDEquipmentService Message ID: weighFailed Message ID: nominalFailed_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.4 GID-2668588 Gross outside scale range (SR0730.3.6.4)

UI text	Comment
Cannot proceed, since the current scale load is outside the scale's valid range, which may have been determined by the required scale resolution. Current scale load: <value> Your scale load must range between <minimum value> and <maximum value>.	For multi-range scales: one lower range might be allowed, given its higher resolution, however, the final weight might require to switch to the next range with a lower resolution that no longer suffices. Message pack: ow_Weigh<version> Message ID: scaleNotSuitableForWeight_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.5 GID-2668589 Weighing value not allowed (SR0730.3.6.6)

UI text	Comment
The current weight is not compatible with the current mode of the phase. Preparation requires a 0 weight, whereas Weighing requires a weight greater than 0.	Message pack: ow_Weigh<version> Message ID: IllegalWeightForCurrentMode_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.6 GID-2668590 No ingoing material identified (SR0730.3.6.7)

UI text	Comment
Cannot proceed, since no sublots of ingoing material have been identified yet.	Message pack: ow_Weigh<version> Message ID: NoOSIIdentifiedYet_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.7 GID-2668591 Warehouse error (SR0730.3.6.8)

UI text	Comment
A warehouse error has occurred while completing the position. <Error message from the warehouse system>	Message pack: wd_UIMessage<version> Message ID: FinishPositionWarehouseError_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.8 GID-2668592 Missing warehouse exception recording (SR0730.3.6.9)

UI text	Comment
Record the warehouse error before you continue processing.	Message pack: wd_UIMessage<version> Message ID: SignWarehouseError_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9 Output Variables (SR0730.9+)

The following output variables are available to reference the phase's output.

7.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

7.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

7.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

7.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

7.9.5 GID-2668597 Used scale (SR0730.9.1)

- Data type: IMESS88Equipment
- Usage: The output variable provides the complete object of the used scale (equipment entity). This is the output to use in subsequent phases for accessing data of the equipment object (e.g. value of the runtime property of the **Current Load (RS)** purpose).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9.6 GID-2668598 Target container object (SR0730.9.4)

- Data type: IMESS88Equipment
- Usage: The output variable provides the complete object of the target container. This is the output to use in subsequent phases for accessing data of the target container.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9.7 GID-2668599 Target container ID (SR0730.9.2)

- Data type: String
- Usage: The output variable provides the identifier of the target container. This is the output to use in subsequent phases for accessing the target container (e.g. target logistic unit of the **Load logistic unit** phase).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9.8 GID-2668600 Sublot identifiers (SR0730.9.3)

- Data type: String
- Usage: The output variable provides a comma-separated list of the identifiers of all closed target sublots. The separator is configurable with the **OutputSeparator** configuration key.

For configuration details, see chapter "Configuration Keys of PharmaSuite" in Volume 4 of the "Technical Guide Configuration and Extension" [A6] (GID-2668114).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8 Release Scale Phase (SR0740+)

The **Release scale** phase (O Release Scale) checks whether the scale value returns back to zero after unloading. The purpose of this phase is to ascertain that no loose material is left on the scale once the load with the recorded weight has been removed.
When the operator confirms the release of the scale, the phase sends a **delete tare** command to the scale.
For a manual scale, the operator enters the final scale value manually. No commands are sent to the scale.
During the calculation of the release result, tolerances are applied according to the resolution factor of the scale multiplied with the resolution defined for the lowest range of the scale that is about to be released.
The **Release scale** phase is skipped if the scale remains loaded.
If the **Quantity entry** weighing method is selected, the phase is skipped.
Details of the release process are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report.
Anomalies that occur during processing are covered by the phase exception handling (e.g. enter scale value manually, not successful release of the scale).
After completion it indicates as release status whether the check passed or failed, both in the Execution Window and in the Navigator.

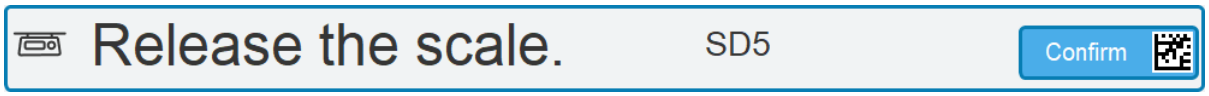

Figure 22: Release scale during execution

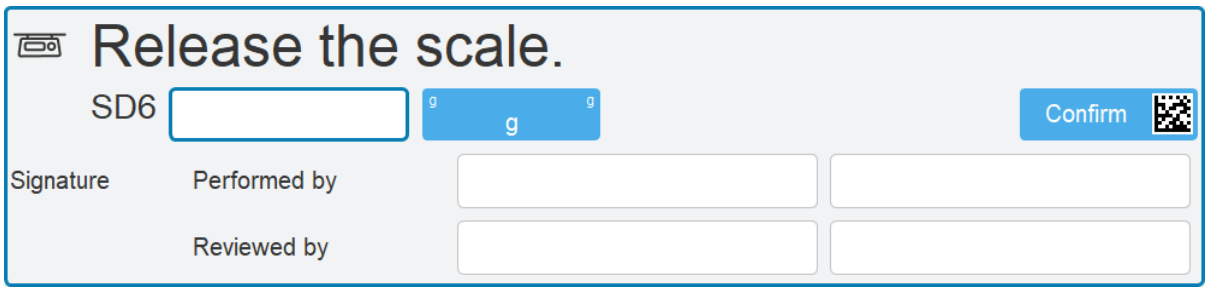

Figure 23: Release scale during execution

8.1 Layout

The phase provides individual layouts for its representation during execution (GID-2668601), in the Navigator (GID-2668602), and in the sub-report (GID-2668603).

8.1.1 Representation during Execution (SR0740.1+)

The representation during execution depends on the phase mode.

8.1.1.1 GID-2670031 Preview mode (SR0740.1.1)

1. Phase-specific icon.
2. <Instruction text>
   (taken from **Instruction (SR0740.8.1)** process parameter (GID-2672062))
3. Placeholder for selected scale
4. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.1.2 GID-2670032 Active mode (SR0740.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0740.8.1)** process parameter (GID-2672062))
4. <Identifier of selected scale>
5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.1.3 GID-2670033 Active mode (manual scale) (SR0740.1.4)

This representation applies to all weighing methods if the selected scale is configured as manual scale.

If a phase completion signature is assigned to the phase, the signature is ignored during execution. Instead, a phase completion signature is added automatically according to the system configuration.

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. <Instruction text>
   (taken from **Instruction (SR0740.8.1)** process parameter (GID-2672062))
4. <Identifier of selected scale>
5. Input box and **UoM** toggle button.
   - The **UoM** toggle button provides all UoMs that are supported by the manual scale.

6. Phase completion signature panel
   - **WD_ES_MANUAL_SCALE** access privilege
7. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.1.4 GID-2670034 COMPLETED MODE (SR0740.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)
2. Phase-specific icon.
3. Release status
4. <"Check passed", "Check failed">
5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.2 Representation in Navigator (SR0740.4+)

The Navigator provides the following details:

8.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>
  - Example:
    Release Scale

8.1.2.2 GID-2670036 INFORMATION COLUMN (SR0740.4.1)

- <Result: "Check passed", "Check failed">
  - Example:
    Check passed

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.2.3 Action column

- There are no actions available.

8.1.3 Representation in Sub-report (SR0740.5+)

The sub-report contains the following information:

8.1.3.1 Common sub-report elements (Framework capability)

- <Start time>
- <Completion time>
- <Unit procedure> / <operation> / <phase>
- <Work center> / <station> / <device> - <phase completion user>

8.1.3.2 GID-2670039 Sub-report elements (SR0740.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)
- Position: <number>
- Release check: <"Check passed", "Check failed">
- Scale value: <scale value>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.2 Business Logic (SR0740.2+)

The phase implements the following business logic.

8.2.1 Main Path

Business logic related to the main path:

8.2.1.1 GID-2670040 Release by scan (SR0740.2.1)

- Function: Release of scale by use of barcode scan
- Type: Main path
- Trigger: Operator scans scale, scale has been released, target container has been removed
- Postcondition: Phase is completed

Step	#	Description
Operator scans scale	5	Phase reads scanned data.
	10	▪ If barcode reading was technically successful, phase updates background color of phase representation according to style sheet in order to confirm the reading. ▪ If barcode reading was technically not successful, phase remains in listening mode.
	20	If barcode does not reflect barcode attribute of the selected scale, phase displays the **Wrong scale (SR0740.3.6.2)** error message (GID-2668611).
	30	▪ Does not apply if scale is configured as manual scale. If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the **Scale driver error (SR0740.3.6.3)** error message (GID-2668612).
	40	▪ Does not apply if scale is configured as manual scale. Phase sends **delete tare** command to scale. This results in an expected scale display of zero (within defined tolerances).
	45	Phase reads and records scale value once. Phase runs the following check: ▪ ABS (Current scale value) < Resolution factor(Scale) x Resolution (Scale) In case of multi-range scales, the scale resolution of the lowest range applies.
	50	If scale value is not within the tolerances, phase creates the **Release was not successful (SR0740.3.2.1)** system-triggered exception (GID-2670040). Otherwise continue with step 70.
	55	If scale value is not within the tolerances, operator canceled exception dialog and thus did not record the **Release was not successful (SR0740.3.2.1)** system-triggered exception (GID-2670049), phase does not read a new scale value, but keeps the scale value from the first time.
	70	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.2.1.2 GID-2670041 RELEASE BY BUTTON (SR0740.2.2)

- Function: Release of scale by use of button
- Type: Main path
- Trigger: Operator confirms phase, scale has been released, target container has been removed
- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	30	▪ Does not apply if scale is configured as manual scale. If no communication can be established to the scale or any other scale driver-related error occurs, phase displays the **Scale driver error (SR0740.3.6.3)** error message (GID-2668612).
	40	▪ Does not apply if scale is configured as manual scale. Phase sends **delete tare** command to scale. This results in an expected scale display of zero (within defined tolerances).
	45	Phase reads and records scale value once. Phase runs the following check: ▪ ABS (Current scale value) < Resolution factor(Scale) x Resolution (Scale)
	50	If scale value is not within the tolerances, phase creates the **Release was not successful (SR0740.3.2.1)** system-triggered exception (GID-2670049). Otherwise continue with step 70.
	55	If scale value is not within the tolerances, operator canceled exception dialog and thus did not record the **Release was not successful (SR0740.3.2.1)** system-triggered exception (GID-2670049), phase does not read a new scale value, but keeps the scale value from the first time.
	70	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.2.1.3 GID-2670042 RELEASE (MANUAL SCALE) (SR0740.2.4)

Applies only if scale is configured as manual scale.

- Function: Release of a scale that is configured as manual scale
- Type: Main path

- Trigger: Phase becomes active, scale has been released, target has been removed
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays the **Active mode (manual scale) (SR0740.1.4)** layout (GID-2670033).
	20	Operator enters current scale value manually.
Phase completion	30	Either manually with the **Release by button (SR0740.2.2)** function (GID-2670041)or by scanning the scale barcode with the **Release by scan (SR0740.2.1)** function (GID-2670040).
Phase completion signature	40	Pre-defined phase completion signature is requested according to the **WD_ES_MANUAL_SCALE** access privilege. Any other phase completion signature that has been assigned to the phase is ignored.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.2.1.4 GID-2670043 SCALE LOADED (SR0740.2.3)

- Function: Scale is loaded
- Type: Main path
- Trigger: Phase becomes active
- Postcondition: N/A

Step	#	Description
Used scale's property of the **Current Load (RS)** purpose is not empty.	10	Phase is skipped. **Release check result (SR0740.9.2)** output variable (GID-2668617) is set to SKIPPED.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.2.2 Weighing Method-specific Paths

There are no specifics available for any of the supported weighing methods.

8.3 Recipe Parameters

The phase provides process parameters (GID-2668606).

8.3.1 Process Parameters (SR0740.8+)

The following process parameters define the behavior of the phase.

8.3.1.1 Instruction Table-specific Parameters

8.3.1.1.1 Instruction table definition (Framework capability)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

8.3.1.1.2 Instruction table text (Framework capability)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

8.3.1.2 Instruction Link-specific Parameters

8.3.1.2.1 Instruction text with links (Framework capability)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2672061). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

8.3.1.2.2 Instruction link definition (Framework capability)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

8.3.1.3 Basic Parameters

8.3.1.3.1 GID-2672062 Instruction (SR0740.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.1.4 Configuration of System-triggered Exceptions

8.3.1.4.1 GID-2672063 Release check (SR0740.8.2)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Release was not successful (SR0740.3.2.1)** system-triggered exception (GID-2670049).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.1.4.2 GID-2672064 UNFORESEEN RESUME (SR0740.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Unforeseen resume (SR0740.3.2.2)** system-triggered exception (GID-2670051).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.1.5 CONFIGURATION OF USER-TRIGGERED EXCEPTIONS

8.3.1.5.1 GID-2672065 ENTER SCALE VALUE MANUALLY (SR0740.8.3)

Does not apply if scale is configured as manual scale.

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Enter scale value manually (SR0740.3.1.1)** user-triggered exception (GID-2670053).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.4 Exceptions (SR0740.3+)

The phase supports user-defined, user-triggered (GID-2668608), system-triggered (GID-2668607), and post-completion exceptions (GID-2668609)and their configuration by means of process parameters (GID-2668606).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

8.4.1 System-triggered Exceptions (SR0740.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

8.4.1.1 GID-2670049 Release was not successful (SR0740.3.2.1)

Representation of the exception:

- <Exception text>
  (taken from **Release check (SR0740.8.2)** process parameter (GID-2672063))
  Expected value between <lower value> and <upper value>.
  Actual value: <scale value>
  - Example:
    Release check performed.
    Expected value between -0.02 kg and 0.02 kg.
    Actual value: 0.04 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.1.2 GID-2670050 Release was not successful - Logic (SR0740.3.2.1.1)

- Trigger: Scale value is not within the release tolerances
- Postcondition: If no exception has been recorded, the already recorded value from the scale is no longer updated

Step	#	Description
Operator triggers exception	10	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.1.3 GID-2670051 Unforeseen resume (SR0740.3.2.2)

Representation of the exception:

- <Exception text>
  (taken from **Unforeseen resume (SR0740.8.4)** process parameter (GID-2672064))
  The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
  Consider to replace the affected position.
  - Example:
    A critical resume situation has occurred. Contact your supervisor before proceeding.
    The system has been resumed during weighing. It must be ensured that the data recorded so far matches the physical situation on the shop floor.
    Consider to replace the affected position.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.1.4 GID-2670052 Unforeseen resume - Logic (SR0740.3.2.2.1)

- Trigger: Output Weighing process has been interrupted so that the system needs to be resumed
- Postcondition: Phase is back in active mode

Step	#	Description
Phase activation	10	Phase displays the **Unforeseen resume (SR0740.3.2.2)** system-triggered exception.
Operator triggers exception	30	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.2 User-triggered Exceptions (SR0740.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

8.4.2.1 GID-2670053 ENTER SCALE VALUE MANUALLY (SR0740.3.1.1)

Does not apply if scale is configured as manual scale.

The **Enter scale value manually** exception allows an operator to enter the scale value of the unloaded scale manually.

Representation during exception handling:

- Instruction:
  Enter the scale value manually.
  Confirm button.
- Exception text:
  <Exception text>
  (taken from **Enter scale value manually (SR0740.8.3)** process parameter (GID-2672065))
  Scale value: <entered value>
  - Example:
    Scale value entered manually.
    Scale value: 0.01 kg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.2.2 GID-2670054 ENTER SCALE VALUE MANUALLY - LOGIC (SR0740.3.1.1.1)

Does not apply if scale is configured as manual scale.

- Trigger: Exception is selected
- Postcondition: Scale value is not updated anymore

Step	#	Description
Operator triggers exception	10	Phase displays Exception Window.
	20	Operator enters current scale value manually.
Operator confirms exception	30	Phase records the exception. Phase performs checks as listed for the **Release by scan (SR0740.2.1)** function (GID-2670040). Phase is ready for completion.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

8.5 Information Messages

There are no information messages available.

8.6 Questions

There are no questions available.

8.7 Decisions

There are no decisions available.

8.8 Error Messages (SR0740.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

8.8.1 GID-2668610 Scale online error (SR0740.3.6.1)

UI text	Comment
A scale communication error has occurred at the <scale> scale.	Message pack: wd_UIMessage<version> Message ID: scalesCommunication_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.2 GID-2668611 Wrong scale (SR0740.3.6.2)

UI text	Comment
You have scanned another scale than selected. Scan the previously selected scale to proceed.	Message pack: wd_UIMessage<version> Message ID: WrongScale_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.3 GID-2668612 Scale driver error (SR0740.3.6.3)

UI text	Comment
Cannot obtain a stable reading or a scale communication error has occurred. Please try again.	Message pack: srv_eqm.WDEquipmentService Message ID: errorDuringTareClear_ErrorMsg Message ID: weighFailed

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.9 Output Variables (SR0740.9+)

The following output variables are available to reference the phase's output.

8.9.1 Instance count (Framework capability)

- Data type: Long
- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

8.9.2 Start time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the start time of the phase.

8.9.3 Completion time (Framework capability)

- Data type: Timestamp
- Usage: The output variable provides the completion time of the phase.

8.9.4 Identifier (Framework capability)

- Data type: String
- Usage: The output variable provides the identifier of the phase.

8.9.5 GID-2668617 Release check result (SR0740.9.2)

- Data type: String
- Values: PASSED, FAILED
- Usage: The output variable provides the result of the release check performed for the scale:
  - The value is PASSED if the current scale load is within the permitted tolerance band around zero and the check has thus passed successfully.
  - The value is FAILED if the check has failed.
  - The value is SKIPPED if the phase was skipped.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A2	FT PharmaSuite Functional Requirement Specification Workflow Phases	PSFRSWF-RM007A-EN-E
A3	FT PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM009B-EN-E
A4	FT PharmaSuite Functional Requirement Specification Data Management	PSFRSDM-RM007B-EN-E
A5	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E
A6	FT PharmaSuite Technical Guide Configuration & Extension - Volume 4	PSCEV4-GR011B-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

10 Document Information

The document information covers various data related to the document.

10.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Martin Kühne	Technical Lead
Ignaz Wangler	Test Lead

10.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
O Manage Produced Material	11.1
O Select Scale	11.1
O Identify Container	11.1
O Tare	11.1
O Weigh	11.1
O Release Scale	11.1
Functional Requirement Specification	1.0

11 Appendix A - Revision History

11.1 Updated Requirements

GID-2668052 Output Weighing Operation

GID-2671995 Instruction (SR0700.8.1)

GID-2669899 Automated scale selection (SR0710.2.1)

GID-2672010 Instruction (SR0710.8.1)

GID-2669917 Preview mode (SR0750.1.1)

GID-2672019 Instruction (SR0750.8.1)

GID-2672036 Instruction (SR0720.8.1)

GID-2668573 Allow override reference tare (SR0720.11.1)

GID-2670002 Finalize target sublot (SR0730.2.5)

GID-2672047 Instruction (SR0730.8.1)

GID-2668600 Sublot identifiers (SR0730.9.3)

GID-2672062 Instruction (SR0740.8.1)

11.2 Added Requirements

None

11.3 Deleted Requirements

None

12 Index

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

Y